Bond University

DOCTORAL THESIS

Lifestyle management of chronic kidney disease: Telehealth strategies for effective self-management.

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Thesis

Lifestyle management of chronic kidney disease: Telehealth strategies for effective self-management

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Abstract

Background: The dietary self-management of chronic kidney disease (CKD) is complex. People with CKD are advised to follow dietary recommendations that restrict individual nutrients, however these interventions have been described by people as confusing and an intense burden to follow. Emerging evidence suggests that improving the overall dietary pattern may attenuate cardiovascular risk, morbidity and mortality in people with CKD. Changing dietary patterns is a complex intervention, which may be facilitated utilising telehealth. Telehealth interventions may overcome patient-centred barriers to face-to-face programs and provide a feasible, ubiquitous and accessible solution. However, a telehealth-delivered dietary pattern intervention has not been tested in the CKD population.

Aim: The aim of this thesis was to develop and test the feasibility and acceptability of a patient-centred telehealth program for the dietary management of CKD.

Methods: Several different methods were utilised to address the aim of this thesis. In the first study, a narrative review of the literature is described, exploring potential dietary interventions in CKD that go beyond the common single nutrient restrictions. Two systematic reviews and meta-analyses were then conducted. The first systematic review explores the association between healthy dietary patterns and all-cause mortality or progression to end-stage kidney disease, by aggregating all existing CKD cohort studies and performing a meta-analysis. The second systematic review investigates the effectiveness of telehealth-delivered dietary interventions in chronic disease evaluated in randomised controlled trials. The fourth study is a qualitative investigation utilising focus groups to explore the experiences of people with CKD with dietary recommendations and the potential to use telehealth for dietary self-management. These projects were used to inform the development of a telehealth-delivered dietary intervention for people with CKD (titled ENTICE-CKD). The ENTICE-CKD study was a six-month pilot randomised controlled trial to explore the feasibility, acceptability, safety, and potential effectiveness of improving dietary quality and clinical parameters utilising a telehealth-delivered dietary program in people with stage 3-4 CKD. The intervention group received fortnightly phone calls for three months and weekly tailored text messages for six months to assist with the implementation of a diet consistent with the Australian Dietary Guidelines. The control group received usual care for three months followed by a non-tailored education-only text message intervention for three months.

Results: The narrative review highlighted the potential for a healthy dietary pattern to improve renal outcomes. This dietary approach may be attractive for several reasons, including the potential to be more comprehendible to people with CKD.

The systematic review of healthy dietary patterns identified six existing CKD cohort studies (n=15,285 participants). A meta-analysis found a healthy dietary pattern was associated with reduced risk of all-cause mortality (relative risk 0.73, 95% confidence interval [CI] 0.63 to 0.83), but no consistent association with end-stage kidney disease was found. There was no standardised dietary pattern, however, diets were generally higher in fruit and vegetables, fish, legumes, cereals, whole grains, and fibre and lower in red meat, salt, and refined sugars compared to reference diets.

The systematic review of telehealth-delivered dietary interventions identified a total of 25 studies (n=7,384 participants) eligible for inclusion, with study duration ranging from eight weeks to eight years. Telehealth interventions were effective in chronic disease dietary management, specifically for improving diet quality (Standardised Mean Difference [SMD] 0.22, 95%CI 0.09 to 0.34]), fruit and vegetable intake (Mean Difference [MD] 1.04 servings/day, 95%CI 0.46 to 1.62), and dietary sodium intake (SMD -0.39, 95%CI -0.58 to, -0.20). Half (52%; n=13) of the included studies were conducted utilising the telephone, and 16% (n=4) using mobile phone text messaging. Other forms of telehealth were less commonly utilised for chronic disease dietary management. No randomised controlled trials conducted in CKD populations were identified.

The qualitative study comprised five focus groups involving 21 people with CKD (and 3 carers; n=24 participants). Key findings were that people with CKD experience an array of barriers and facilitators to achieving their dietary recommendations, and these were reported across five primary themes: 1) Exasperating stagnancy (where people feel patronised by redundant advice, confused and unprepared for dietary change, feel there is an inevitability of failure, and many barriers to accessing dietetic services); 2) Supporting and sustaining change (where people prefer receiving regular feedback, getting incremental and comprehendible dietary modification, practical guidance on food, receive services with flexibility in monitoring schedule, and valuing peer advice); 3) Fostering ownership (seeking kidney diet information, enacting behaviour change, making reminders, and tracking progress against targets); 4) Motivators and positive learning instruction (relying on reassurance, positive reinforcement, wanting clinicians to focus on allowable foods, and involving their family); 5)

Threats and ambiguities of risk (where people view sugar as the culprit in their diet, experience ubiquity of salt, difficulty with illegible food labelling, wanting to avoid processed foods, and questioning credibility of sources where appropriate). Participants were open to using telehealth to support their dietary recommendations, with each of the five themes having important sub-themes related to using telehealth for dietary self-management.

The collective results of the narrative review, two systematic reviews, as well as the qualitative study were used to inform the development of a telehealth-delivered dietary intervention specific for people with CKD. The telephone and mobile phone were identified as the best delivery methods, as participants in the qualitative study were most comfortable using these telehealth modalities. The delivery schedule was decided to be fortnightly with weekly text messages to ensure contact and feedback was regular, and the diet advice was not restriction focused, but was comprehensive and delivered in steps across each phone call.

Eighty participants were recruited for the ENTICE-CKD pilot trial. The intervention was shown to be feasible and acceptable by participants. The trial had good retention with 93% and 98% remaining in the intervention and control groups for the six-month study duration, respectively. The intervention was successfully delivered to protocol, and 96% of all planned intervention calls were completed. All (100%) participants in the intervention group viewed the tailored text messages as acceptable in supporting their dietary change, compared to 27 participants (69%) in the non-tailored education-only text messages (control) group. At three months, participants in the intervention group improved the proportion of calories from the core (non-discretionary) food groups (5.2%, 95% CI 0.6 to 9.9) that they consumed, increased vegetable intake (1.4 serves, 95% CI 0.6 to 2.1] per day), increased dietary fibre intake (5.5 grams, 95% CI 2.7 to 8.2] per day), and reduced body weight (-1.7kg, 95% CI -3.1 to -0.3]) compared to the control group. At six months, only the proportion of calories from core (non-discretionary) foods consumed by participants remained significant (4.3%, 95% CI 0.3 to 8.2]) compared to the control group. No adverse events related to the intervention were reported throughout the study.

Conclusion: The research conducted as part of this thesis shows that a telehealth-delivered intervention to improve diet quality may be feasible, acceptable, safe and effective for stage 3-4 CKD dietary self-management. This research addresses important gaps in the literature, can be used to inform public policy about the use of telehealth in chronic disease management. A large-scale randomised controlled trial to determine the effectiveness of the

ENTICE-CKD program on patient-centred quality of life, and renal and cardiovascular outcomes is now needed.

Keywords

Chronic kidney disease

Renal disease

Diet

Dietary patterns

Telehealth

Telephone

Mobile

Statement of originality

I herewith confirm that the research presented within this thesis has not been previously submitted for the award of a degree or diploma at any university or educational institution. This thesis contains original material which is my own work, and to the best of my current knowledge, is only published ahead of thesis submission to reputable peer reviewed journals, where due reference is clearly made. Jaimon Kelly is the sole author of Chapter 1, 2, 8 and 9, and was the lead author on the manuscripts presented in Chapters 3, 4, 5, 6, and 7. For these published works contained in this thesis, Jaimon Kelly was the lead author, produced the initial manuscript drafts, and was responsible for integrating and finalising all co-author input.

I acknowledge that the copyright of all material contained in my thesis resides with the copyright holder(s) of that material. I herewith confirm that have obtained copyright permission from the original copyright holders, where appropriate, to reproduce material in this thesis.

Signed: ______________________________ Dated: 30 April 2018

Mr. Jaimon Kelly, APD
PhD Candidate

Publications during candidature

During three years of candidature, the candidate has lead authored five published manuscripts which directly contribute to this thesis. The candidate has been the lead author for a further two manuscripts which directly contribute to this thesis and are either under review for publication (Chapter 7), or in draft to be submitted for publication (Chapter 8). In addition, the candidate has been involved in 14 other publications, which are either complementary contributions to the aim of this thesis (but not directly related), or a co-authored publication which has augmented the candidates research development during PhD candidature.

Please refer to the following legend:

1. **Bold** denotes the Candidate
2. Underline denotes the presenting author for a conference abstract

Manuscripts directly contributing to this thesis

1. **Kelly JT**, Reidlinger DP, Hoffmann TC, Campbell KL. Telehealth methods to deliver dietary interventions in adults with chronic disease: a systematic review and meta-analysis. *American Journal of Clinical Nutrition.* 2016; 104(6), 1693–1702. [Chapter 5]
2. **Kelly JT**, Palmer SC, Wai SN, Rouspo M, Carrero JJ, Campbell KL, Strippoli GFM. Healthy dietary patterns and risk of mortality and ESRD in CKD: A meta-analysis of cohort studies. *Clinical Journal of the American Society of Nephrology.* 2016; 12(2), 272-279. [Chapter 4]
3. **Kelly JT**, Rossi M, Johnson DW, Campbell KL. Beyond sodium, phosphate and potassium: potential dietary interventions in kidney disease. *Seminars in Dialysis.* 2017; 30(3), 197-202. [Chapter 3]
4. **Kelly JT**, Campbell KL Hoffmann TC, Reidlinger DP. Patient experiences of dietary management in chronic kidney disease: A focus group study. *Journal of Renal Nutrition*. 2017.[In-press] [Chapter 6]
5. **Kelly JT**, Reidlinger DP, Hoffmann TC, Campbell KL. Telehealth methods to deliver multifactorial dietary interventions in adults with chronic disease: A systematic review protocol. *Systematic Reviews.* 2015; 4(1), 1-7. [Appendix A]

Manuscripts [in-preparation or submitted] directly contributing to this thesis

1. **Kelly JT**, Warner MM, Conley M, Reidlinger DP, Hoffmann TC, Craig J, Tong A, Reeves M, Johnson DW, Palmer S, Campbell KL. The evaluation of individualized telehealth intensive coaching to promote healthy eating and lifestyle in chronic kidney disease (ENTICE-CKD): A mixed methods process evaluation. [Under review by the *Journal of the Academy of Nutrition and Dietetics*]. [Chapter 7]
2. **Kelly JT**, Conley M, Reidlinger DP, Hoffmann TC, Craig J, Tong A, Reeves M, Johnson DW, Palmer S, Campbell KL. A dietary coaching program to improve dietary quality and clinical outcomes in CKD: The ENTICE-CKD randomized controlled trial. [Draft manuscript to be submitted]. [Chapter 8]
3. Warner MM, **Kelly JT**, Reidlinger DP, Tong A, Campbell KL. Patient acceptability and experiences of a telehealth coaching program to improve diet quality in CKD: A semi-structured interview study. [Draft manuscript to be submitted] [Appendix B]

Conference presentations directly contributing to this thesis

Oral Presentations

1. **<u>Kelly JT</u>**, Reidlinger DP, Hoffmann TC, Campbell KL. Patient perception on diet and telehealth: *International Congress on Nutrition and Metabolism in Renal Disease*; 23 April 2016; Okinawa, Japan.
2. **<u>Kelly JT</u>**, Reidlinger DP, Hoffmann TC, Campbell KL. Telehealth methods to deliver multifactorial dietary interventions in adults with chronic disease: A systematic review. *Research Week: Bond University Higher Degree by Research Conference*; 16 November 2015; Queensland, Australia.
3. **<u>Kelly JT</u>**. Lifestyle management of chronic kidney disease: telehealth strategies for effective self-management. *South East Queensland Higher degree by Research Nutrition Summit*; 9 Dec ember 2015; Queensland, Australia.
4. **<u>Kelly JT</u>**, Wai SN, Rouspo M, Carrero JJ, Strippoli GFM, Palmer SC, Campbell KL. Healthy eating patterns, mortality and end-stage kidney disease in CKD: A systematic review and meta-analysis. *Nephrology*. 2016; 21(Supp S2), 58-149. (Presented at the Asian Pacific Congress of Nephrology; 20 September 2016; Perth, Western Australia).
5. <u>Palmer SC</u>, **Kelly JT**, Campbell KL, Wai SN, Carrero JJ, Rouspo M, Strippoli GFM. Healthy eating patterns, mortality and end-stage kidney disease in CKD: A systematic

review and meta-analysis. *Journal of the American Society of Nephrology*. 2016; 27(Abstract edition), 16A. (Presented at the American Society of Nephrology; 11 November 2016; Chicago, Illinois).

6. **Kelly JT**, Campbell KL, Wai SN, Carrero JJ, Rouspo M, Palmer SC, Strippoli GFM. Healthy eating patterns, mortality and end-stage kidney disease in CKD: A systematic review and meta-analysis. *Research Week: Bond University Higher Degree by Research Conference*; 16 November 2015; Queensland, Australia. *(Awarded Best Oral Presentation)*
7. **Kelly JT,** Tong A, Hoffmann TC, Campbell KL, Reidlinger, DP. Perspectives on dietary self-management and telehealth in chronic kidney disease. *Gold Coast Health Medical Research Conference*; 2 December 2016; Queensland, Australia.
8. **Kelly JT**, Reidlinger DP, Hoffmann TC, Campbell KL (2017). Can telehealth methods achieve multifactorial dietary change in adults with chronic disease? *Nutrition & Dietetics*. 2017; 74(Supp 1), 22. (Presented at the Dietitians Association of Australia 34th National Conference; 18 May 2017; Hobart, Australia).
9. **Kelly JT**, Conley M, Warner MM, Reidlinger DP, Hoffmann T, Johnson DW, Reeves M, Tong A, Palmer SC, Campbell KL. Is a telehealth intervention feasible to improve dietary quality in chronic kidney disease? Process evaluation results from a pilot randomised controlled trial. (Accepted for oral presentation at the Dietitians Association of Australia 35th National Conference; May 2018; Sydney, Australia).
10. Warner MM, **Kelly JT**, Reidlinger DP, Tong A, Campbell KL. A telehealth program for dietary management of CKD: Is it accepted by patients? (Accepted for oral presentation at the Dietitians Association of Australia 35th National Conference; 17 May 2018; Sydney, Australia).
11. **Kelly JT**, Conley M, Reidlinger DP, Hoffmann T, Johnson DW, Palmer SC, Campbell KL. Is a telehealth coaching for dietary change in chronic kidney disease: The ENTICE randomized controlled trial. (Accepted for oral presentation at the 29th International Congress on Nutrition and Metabolism in Renal Disease; June 2018; Genova, Italy).

Poster Presentations

1. **Kelly JT**, Reidlinger DP, Hoffmann TC, Campbell KL. Telehealth methods to deliver multifactorial dietary interventions in adults with chronic disease: A systematic review. *Gold Coast Health Medical Research Conference*; 3 December 2015; Queensland, Australia.

2. Wai SN, **Kelly JT**, Johnson DW, Campbell KL. Dietary patterns and clinical outcome in chronic kidney disease: CKD.QLD Nutrition Study: *International Congress on Nutrition and Metabolism in Renal Disease*; 23 April 2016; Okinawa, Japan.
3. **Kelly JT,** Tong A, Hoffmann TC, Campbell KL, Reidlinger, DP. Patient experiences with dietary prescriptions and opportunities for telehealth to facilitate dietary change. *Nephrology*. 2016; 21(Supp S2), 150-280. (Presented at the Asian Pacific Congress of Nephrology; 19 September 2016; Perth, Western Australia).
4. Warner MM, **Kelly JT**, Reidlinger DP, Hoffmann TC, Campbell KL. Reporting of telehealth-delivered dietary intervention trials in chronic disease: A systematic review. (Accepted for poster presentation at the Dietitians Association of Australia 35th National Conference; 18 May 2018; Sydney, Australia).

Additional manuscripts and book chapters published during candidature

1. **Kelly J**, Khalesi S, Dickinson K, Hines S, Coombes J, Todd A. The effect of dietary sodium modification on blood pressure in adults with systolic blood pressure less than 140 mmHg: A systematic review. *JBI Database of Systematic Reviews and Implementation Reports.* 2016; 14(6), 196-237.
2. Wai SN, **Kelly JT**, Johnson DW, Campbell KL. Dietary Patterns and Clinical Outcomes in Chronic Kidney Disease: The CKD.QLD Nutrition Study. *Journal of Renal Nutrition.* 2016; 27(3), 175–182.
3. **Kelly JT**, Campbell KL, Carrero JJ. Handbook of Nutrition and the Kidney (Mitch & Ikizler) 7th Edition; Chapter 7: Role of Nutrition in Cardiovascular and Kidney Disease. Lippincott Williams & Wilkins, 2017.
4. Odgers-Jewell K, Ball L, **Kelly JT**, Isenring E, Reidlinger D, Thomas R. Effectiveness of group-based self-management education for individuals with Type 2 diabetes: A systematic review with meta-analyses and meta-regression. *Diabetic Medicine*. 2017; 34(8),1027–1039
5. **Kelly JT**, Carrero JJ. Dietary Sources of Protein and Chronic Kidney Disease Progression: The Proof May Be in the Pattern. *Journal of Renal Nutrition*. 2017; 27(4), 221-224.
6. Todd A, Walker RJ, MacGinley RJ, **Kelly J**, Major T, Merriman T, Johnson RJ. Dietary sodium modifies serum uric acid concentrations in humans. *American Journal of Hypertension*. 2017; 30(12), 1196-1202.

7. Warner M, **Kelly JT**, Reidlinger DP, Hoffmann TC, Campbell KL. Reporting of telehealth-delivered dietary intervention trials in chronic disease. *Journal of Medical and Internet Research.* 2017; 19(12): e410.
8. Marx W, Teleni L, Opie RS, **Kelly JT**, Isenring L. Efficacy and effectiveness of carnitine supplementation for cancer-related fatigue: A systematic literature review and meta-analysis. *Nutrients*. 2017; 9(11), 1224.
9. Marshall S, Craven D, **Kelly JT**, Isenring E. A systematic review and meta-analysis of the criterion validity of nutrition assessment tools for diagnosing protein-energy malnutrition in the older community setting (the MACRo study). *Clinical Nutrition*. 2017.[In-press]
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12. Marx W, **Kelly JT**, Crichton M, Craven D, Collins J, Mackay H, Isenring E, Marshall S. Is telehealth effective in managing malnutrition in community-dwelling older adults? A systematic review and meta-analysis. *Maturitas.* 2018; 111: 31-46.
13. Itsiopoulos C, Marx W, Mayr H, Tatucu-Babet O, Dash S, George E, Trakman G, **Kelly JT**, Thomas C, Brazionis L. The role of omega-3 polyunsaturated fatty acid supplementation in the management of type 2 diabetes mellitus: A narrative review. *Journal of Nutrition & Intermediary Metabolism*. 2018. [In-press]
14. Marx W, Cutajar J, Annois B, **Kelly JT**, Tierney A, Papingas A, Scholey A, Itsiopoulos C. The effect of resveratrol on cognitive performance: A systematic literature review. *Nutrition Reviews*. 2018. [In-press]

Ethics declaration

The research associated with this thesis received ethics approval from the following Human Research Ethics Committees (HREC):

Chapter 6

1. Gold Coast University Hospital HREC [EC00160] – application number HREC/15/QGC/90
2. Bond University HREC [EC00357] – application number 0000015284

Chapter 7 and 8

3. Metro South HREC [EC00167] – application number HREC/16/QPAH/349
4. Bond University HREC [EC00357] – application number 0000015805

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Abbreviations

ACE – Angiotensinogen Converting Enzyme

ACM – All-Cause Mortality

ADG – Australian Dietary Guidelines

AER – Albuminuria Excretion Rate

AKTN – Australasian Kidney Trial Network

AQOL-4D – Assessment of Quality of Life – 4 Domain

ARB – Angiotensinogen Receptor Blocker

ARFS – Australian Recommended Food Score

AUD – Australian Dollars

BMI – Body Mass Index

BHC – Better Health Choices

BP - Blood Pressure

CAPD - Continuous Ambulatory Peritoneal Dialysis

CARI – Caring for Australians with Renal Impairment

CI – Confidence Interval

CKD – Chronic Kidney Disease

CONSORT - Consolidated Standards of Reporting Trials

CRIC - Chronic Renal Insufficiency Cohort

CVD – Cardiovascular Disease

DASH – Dietary Approaches to Stop Hypertension

DBP – Diastolic Blood Pressure

DVD – Digital Video Disk

ENTICE-CKD - Evaluation of iNdividualized Telehealth Intensive Coaching to promote healthy Eating and lifestyle in Chronic Kidney Disease

ESKD – End Stage Kidney Disease

ESMO - Effects of Sodium Modification on Outcome

ESRD – End Stage Renal Disease

FFQ – Food Frequency Questionnaire

FTF – Face-to-Face

eGFR – Estimated Glomerular Filtration Rate

g - Grams

GFR – Glomerular Filtration Rate

GRADE - Grading of Recommendations Assessment, Development, and Evaluation

HbA1c – Glycosylated Haemoglobin

HCF - Hospitals Contribution Fund of Australia

HDL – High Density Lipoprotein

HF – Heart Failure

HR – Hazard Ratio

ICTRP - International Clinical Trials Register

IDNT - Irbesartan Diabetic Nephropathy Trial

INTERSALT - International Study on Salt and Blood Pressure

JNC – Joint National Committee

KDIGO – Kidney Disease Improving Global Outcomes

KDOQI - Kidney Disease Outcomes Quality Initiative

kg – Kilograms

KHA – Kidney Health Australia

L – Litres

LDL – Low Density Lipoprotein

MBS – Medicare Benefits Scheme

Min – Minutes

MD – Mean Difference

M-Health – Mobile Health

mg – Milligrams

mL – Millilitres

mmHg – Millimetres of Mercury

NHMRC – National Health and Medical Research Council

NIH-AARP - National Institutes of Health–American Association of Retired Persons

PA – Physical Activity

POWER - Practice-based Opportunities for Weight Reduction

PRISMA - Preferred Reporting Items for Systematic Reviews and Meta-analysis

PROSPERO - International Prospective Register of Systematic Reviews

RCT – Randomised Controlled Trial

RE-AIM – Reach, Efficacy, Adoption, Implementation, Maintenance

RedCap - Research Electronic Data Capture

REIN - Ramipril Efficacy in Nephropathy

RENAAL - Reduction of Endpoints in NIDDM with the Angiotensin II Antagonist Losartan

RevMan – Review Manager

RR – Risk Ratio

SBP – Systolic Blood Pressure

SD – Standard Deviation

SMD – Standardised Mean Difference

SMS – Short Message Service

SPSS - Statistical Package for the Social Science

SPRINT - Systolic Blood Pressure Intervention Trial

TIDieR – Template for Intervention Description and Replication

UK – United Kingdom

US – United States

WHO - World Health Organisation

Chapter 1 - Introduction

Chronic kidney disease (CKD) currently affects 1 in 10 people worldwide (Bello et al., 2017). The burden of CKD individuals experience is complex, as people usually have multiple comorbidities (particularly cardiovascular disease [CVD] and diabetes) (Ong, Jassal, Porter, Logan, & Miller, 2013). These comorbidities are resource intensive across multiple levels of the healthcare system (Sevick et al., 2007). Therefore, CKD follows a substantial impact on people's lives, particularly the considerable time required to invest in the self-management of their diet, lifestyle, medications, and attending multiple specialist appointments (Bonner et al., 2014).

Dietary self-management has long been considered a modifiable risk factor for the progression of CKD. Dietary advice is often multifaceted, complex and requires individualised support (Mozaffarian, 2016; Smyth et al., 2014). However, clinicians are challenged in practice to provide the individualised support with the frequency and consistency required to sustain long-term dietary changes.

Current best-practice guidelines from the Kidney Disease: Improving Global Outcomes (KDIGO) Work Group (Eknoyan et al., 2013), the American Dietetic Association (American Dietetic Association, 2010) and the Australian New Zealand Renal Guidelines Taskforce (Ash et al., 2006) focus on the modification of singular nutrients (e.g. potassium, phosphate and sodium), which have an conflicting evidence-base for impacting on renal and cardiovascular health.

The Caring for Australians with Renal Impairment (CARI) practice guidelines now recommend applying the Australian Dietary Guidelines to reduce risks and complications associated with CKD (Chan & Johnson, 2013). This reflects a paradigm shift in renal nutrition, towards improving overall diet quality through targeting the overall dietary pattern, and away from single nutrient interventions. However, there is paucity of clinical trials to demonstrate the effectiveness of diet quality interventions in CKD. Furthermore, there is no indication as to the level of individualised support and education required to sustain a healthy dietary pattern over the long-term to see the improvements in outcomes demonstrated in these studies (Ricardo et al., 2015; Ricardo et al., 2013).

Following single nutrient recommendations is considered complex and often results in a wide range of conflicting dietary recommendations for other associated commodity risk factors

(Smyth et al., 2014). People with CKD commonly express feeling overwhelmed with dietary information and an intense burden when implementing dietary advice (Palmer et al., 2014). People with CKD express a preference for regular coaching and monitoring to help them understand dietary recommendations and become confident in their ability to self-monitor and manage such changes (Palmer et al., 2014).

With the growing prevalence of CKD, the demand on health services and resources are likewise increasing (Campbell & Murray, 2013). Specialised renal dietitians are lacking in number and patients may experience inconsistencies between treating clinicians. Therefore, regular coaching is not feasible under the current models of healthcare. It is now timely to look to alternative methods of healthcare delivery within current healthcare resources, which facilitate patient-centred care and reduce the barriers that patients face to achieve effective dietary self-management.

Telehealth is an umbrella term that encompasses a whole range of health practice activities, specifically delivered from a distance. Utilising telehealth modalities to provide dietary coaching, particularly through phone-based and text message platforms, provide an alternate framework for frequent and structured contact that is needed to support the complex dietary change required in CKD. The steep trajectory in the use of technology over the last 10 years is well acknowledged (Wootton, 2012). It has been estimated that over 90% of Australians currently have access to some form of telecommunication service (e.g. telephone, mobile, and/or internet), highlighting the potential for such devices to be used to deliver and support dietary education in a widely accessible manner (ACCAN - Australian Communication Consumer Action Network, 2014). Telehealth interventions offer a potential solution to overcome the typical logistical challenges in accessing traditional healthcare services and may assist overcoming patient-centred barriers to implementing dietary recommendations, as they provide people with flexibility and have a high rate of patient acceptability (World Health Organization, 2010). Telehealth interventions may therefore facilitate dietary change through increasing the reach of service, the amount of contact with clinicians and deliver dietary education in an easy to understand format.

There are important questions which remain unanswered in literature available to date (see section 2.7.1 Identification of key gaps in the literature). The associations of healthy dietary patterns to clinical outcomes in CKD have not been systematically summarised. Alternative methods of dietary intervention delivery have not been explored in CKD. While evidence to support the improvement in diet quality in other chronic diseases exists, the wider evidence-base for the effectiveness of telehealth-delivered interventions for complex dietary advice (e.g. changing overall dietary patterns) has not been systematically synthesised to date. Another gap in the current literature is the absence of telehealth-delivered dietary interventions in CKD. Before a telehealth program could be designed and piloted in CKD, adequate patient-engagement is needed to inform such intervention development. Finally, the development and pilot of a telehealth program to improve diet quality in CKD has not been conducted to date, and therefore there is no current knowledge as to the feasibility, acceptability, safety, and possible effectiveness of such an intervention.

1.1 Overarching thesis aim

The overall aim of this thesis is to develop and test the feasibility and acceptability of a patient-centred telehealth program for the dietary self-management of CKD.

1.2 Research questions

This thesis will seek to investigate the following unanswered questions to address the thesis aim:

1. Is a healthy dietary pattern associated with improved survival and reduced risk of end-stage kidney disease in established kidney disease populations?
2. What telehealth programs have been conducted in chronic disease populations; what content has been utilised; and what is their overall effectiveness on facilitating dietary change?
3. What are the greatest challenges people with CKD experience in relation to achieving their dietary recommendations?
4. What do people with CKD perceive as facilitators and barriers to using telehealth to support their dietary self-management?
5. Is telehealth coaching to improve diet quality feasible and acceptable to patients with stage 3-4 CKD?
6. Is a telehealth intervention safe and effective at improving diet quality in people with stage 3-4 CKD?

1.3 Conceptual framework

To address the aim of this thesis, the steps of the m-Health framework were followed for developing and evaluating telehealth interventions (Whittaker, Merry, Dorey, & Maddison, 2012), which details the steps in the development of an m-Health intervention as:

1. Conceptualization;
2. Formative research;
3. Pretesting;
4. Randomised controlled trial; and
5. Qualitative research (interviews).

These steps have the purpose of bringing together experts in the relevant fields, informing the development of the intervention, determining its acceptability, engaging with patient on the content and timing and the data collection process, testing effects in comparison to a control group, and improving the intervention and implementation methods. This framework has been adapted to describe the process in developing a telehealth program in this thesis. This framework is outlined in Table 1-1.

Table 1-1: Framework for the development of a telehealth program in CKD.

Development phase	Method to be used	Purpose	Chapter
Conceptualization	• Advisory group (supervisory team) meetings/discussions • Literature review • Scoped narrative review • Systematic review a. Dietary approaches b. Delivery method	• Experts in the field of nutrition in CKD, chronic disease, and the use of telehealth methods in clinical research • Explore current patient-centred issues with renal nutrition practice in the literature • Establish potential associations of dietary patterns to CKD clinical end-points • Critically appraise the evidence for telehealth methods in chronic disease • Establish the effectiveness of telehealth for complex dietary change in chronic disease	1-5
Formative research	• Focus groups • Cross-sectional survey (not a primary publication of this thesis; available in Appendix C)	• Establish the prevalence of technology use in CKD patients • Determine what types of technology do patients use, or feel comfortable using, and what barriers they might experience to using • Explore patients' perspectives on technology • Explore patients' opinions on using technology to improve self-management	6; Appendix C
Pre-testing	• 'Beta-testing' the developed telehealth program • Quality testing	• Attain feedback from consumer groups and participants involved in the formative stage • Attain feedback from expert clinicians (face validity)	Example in Appendix D
Randomised Controlled Trial	• Randomised controlled trial	• Determine the telehealth program's feasibility, acceptability, safety and effectiveness in improving diet quality in stage 3-4 CKD	7-8
Qualitative research (interviews)	• Follow up interviews with the ENTICE participants	• Determine the telehealth program's acceptability in the stage 3-4 CKD population	7; Appendix B

1.4 Thesis arrangement

Following this introductory chapter, a thorough literature review was performed (Chapter 2) which highlights the key gaps in the literature required to address this thesis' aim. The subsequent 8 distinct, yet interrelated chapters address each of the research questions detailed on page 4, and are arranged into 4 sections, as detailed below.

Section 1: Dietary approaches in CKD

- Chapter 3: Beyond sodium, phosphate and potassium: potential dietary interventions in kidney disease
- Chapter 4: Healthy dietary patterns and risk of mortality and ESRD in CKD: a meta-analysis of cohort studies

Section 2: Telehealth delivery methods for dietary approaches in CKD

- Chapter 5: Telehealth methods to deliver dietary interventions in adults with chronic disease: a systematic review and meta-analysis
- Chapter 6: Patient experiences of dietary management in chronic kidney disease: a focus group study

Section 3: Pilot randomised controlled trial

- Chapter 7: The evaluation of individualized telehealth intensive coaching to promote healthy eating and lifestyle in chronic kidney disease (ENTICE-CKD): a mixed methods process evaluation.
- Chapter 8: A dietary coaching program to improve dietary quality and clinical outcomes in CKD: Results from a pilot randomized controlled trial

Section 4: Overall discussion, future directions and conclusion

- Chapter 9: Discussion and future directions

Chapter 2 - Literature review

2.1 What is Chronic Kidney Disease?

Chronic kidney disease (CKD) is a progressive, degenerative and functional decline in the kidney, that has been evident for at least three months (Eknoyan et al., 2013). Chronic kidney disease is defined by a reduced glomerular filtration rate (GFR) of less than 60ml/min/1.73m^2 or abnormal concentrations of albuminuria, or both (Eknoyan et al., 2013). The Kidney Disease Improving Global Outcomes (KDIGO) Clinical Practice Guidelines (2012) detail two main methods for diagnosing and evaluating CKD; the first is grading the estimated glomerular filtration rate (GFR), measured by blood test and CKD-EPI estimating equation (based on race, sex, and serum creatinine level) (Levey et al., 2009). The second criteria is the albumin excretion rate measured in the urine, and may not necessarily be present with impaired kidney function (Eknoyan et al., 2013). Table 2-1 lists the stages of impaired kidney function and guiding criteria for diagnosing CKD.

Table 2-1: Stages of CKD defined according to GFR and albuminuria categories (Eknoyan et al., 2013).

GFR category	GFR (ml/min/1.73 m^2)	Terms	Action
G I	>90	Normal or high	
G II	60–89	Mildly decreased	Monitor
G3 IIIa	45–59	Mildly to moderately decreased	Monitor – consider AER
G IIIb	30–44	Moderately to severely decreased	Referral – consider AER
G IV	15–29	Severely decreased	Referral
G V	<15	Kidney failure	
Albuminuria categories	**Albumin excretion rate (mg/day)**	**Terms**	**Action**
A I	<30	Normal/mildly increased	
A II	30-300	Moderately increased	Referral – consider eGFR
A III	>300	Severely increased	Referral

Abbreviations: GFR – glomerular filtration rate, AER – albumin excretion rate, ml – millilitre, min – minute

The burden of CKD is multifactorial. Firstly, the prevalence of CKD is growing, currently estimated at 10-11 percent of the adult population worldwide (Bello et al., 2017). It is estimated that less than a third of those with CKD are currently aware they have it (Bello et al., 2017). Secondly, the rising prevalence of CKD is also important due to the increased risk of death. Over 10 percent of Australian deaths are attributable to CKD (Australian Institute of Health and Welfare, Cat. no. AUS 178). Cardiovascular disease (CVD) contributes to over half of the major causes of death in established CKD populations. (Stenvinkel et al., 2008; Tedla, Brar, Browne, & Brown, 2011). Thirdly, the current costs for treatment of people with end-stage kidney disease (ESKD) exceeds one billion Australian dollars (AUD) per year, which is greater than 15% of the Australian Government's total expenditure on health (Australian Institute of Health and Welfare, Cat. no. AUS 178). By 2020, the expected costs to the Australian Government to treat, dialyse or transplant people with ESKD is estimated at 12 billion AUD (Cass et al., 2006).

2.1.1 Cardiovascular disease in CKD: a complex relationship

Chronic kidney disease is often a progressive condition, where complications become more difficult to manage as an individual progress through the stages outlined in Table 2-1. If CKD progression cannot be slowed, then renal replacement therapy (dialysis or renal transplantation) will be required to sustain life. The benefit of delaying CKD progression and limiting CKD-related complications is to reduce the high mortality rates outlined above. However, the reality is that an individual who displays even early stages of CKD is more likely to die of CVD related causes than ESKD (Blood Pressure Lowering Treatment Trialists' Collaboration, 2013; Stenvinkel et al., 2008). Furthermore, CVD risk increases as early as stage 2 CKD, and exponentially increases as kidney function further declines (Vanholder et al., 2005). Undeniably, there is a strong relationship between the kidney and cardiovascular function, and its complexity is only exacerbated as either system further declines. Thus, the mainstay and target for CKD treatment has been to slow the progression of the disease.

There is great complexity to the development of CVD in CKD, involving a magnitude of multifactorial traditional and non-traditional risk factors (Stenvinkel et al., 2008), and it depends on the underlying cause of CKD, especially hypertension (McMahon, Campbell, Bauer, & Mudge, 2015) and diabetes (Tan, Jaung, Gamble, & Cundy, 2014). Evidence supports traditional CVD risk factors to be similarly present in CKD populations and may account for the higher CKD death rate by CVD causes, including hypertension, obesity, smoking, older age, left ventricular hypertrophy (LVH), and dyslipidaemia (Stenvinkel et al., 2008). These factors are central to combating the elevated CVD risks in CKD. However, non-traditional risk factors are emerging as influential to the incidence of CVD in CKD patients

(Muntner, 2004; Stenvinkel et al., 2008). These include a reduced GFR and albuminuria (van der Velde et al., 2011), anaemia (Hörl, 2013), increased inflammatory markers, oxidative stress, protein-energy malnutrition (Stenvinkel et al., 2008), vitamin D deficiency, and elevated serum uric acid (Glassock, Pecoits-Filho, & Barberato, 2009).

2.2 Hypertension, CVD and CKD: Why is blood pressure control important?

The burden of hypertension is considered both a cause and consequence of CKD, and good management is a central strategy to combat the excessive CVD risk in CKD.

Hypertension affects over one-third of Australian adults (National Heart Foundation of Australia, 2008) and in the United States (US) (Garimella & Uhlig, 2013), yet prevalence is substantially higher in CKD (Tedla et al., 2011). Specifically, even in early stage 2-3 CKD, hypertension is prevalent in over half of patients (Tedla et al., 2011). Hypertension may also develop and worsen as kidney function deteriorates, with prevalence reported at 70-85% in stages 4-5 CKD (Cai, Zheng, Sun, & Chen, 2013; Garimella & Uhlig, 2013; Jessani, Bux, & Jafar, 2014; Sarafidis, 2008).

An important body of evidence for the role of hypertension in driving higher CVD prevalence in CKD comes from a prospective collaborative meta-analysis of 150,000 trial participants with and without CKD (Blood Pressure Lowering Treatment Trialists' Collaboration, 2013). Over 15,000 cardiovascular events were recorded, suggesting that a reduction of 5mmHg systolic blood pressure (SBP) reduced the risk of major cardiovascular events by 17% in participants with GFR $\leq$60 mL/min/1.73m^2. This provides vital and compelling evidence for the cardiovascular benefits of reducing blood pressure (BP) in people with stages 2-3 CKD. However, this analysis was limited by the low percentage of participants with stage 4-5 CKD, who comprised less than four percent of the total CKD sample.

A strong predictor of sudden death from CVD in CKD is left ventricular hypertrophy (Glassock et al., 2009; Paoletti et al., 2004; Silberberg, Barre, Prichard, & Sniderman, 1989). This is defined as a physiological adaption to a long-term increase in cardiac workload (from pressure or volume overload), with a prevalence of 75-80% in CKD stages 4 and 5 (Paoletti, Bellino, Cassottana, Rolla, & Cannella, 2005). Hypertension is regarded as a major contributor in the pathogenesis of left ventricular hypertrophy, however other important markers such as endothelial dysfunction have been proposed as a likely mediator (Poulikakos et al., 2014). Increased left ventricular mass index has been associated with acceleration of progression to ESKD in a CKD stage 3 to 4 sample absent of diabetes or severe ischaemic heart disease (Paoletti et al., 2011).

Thus, with a complex relationship between CKD and CVD, controlling BP is an essential modifiable risk factor in attenuating the risk for CVD in CKD (Elliott, McCaughan, & Fogarty, 2014), and is a focal medical treatment target by general practitioners and treating nephrologists.

2.2.1 Blood pressure targets for the medical management of CKD

Elevated BP follows a strong link and risk for CVD. As such, BP targets have long been debated in nephrology to control the elevated CVD risk. Table 2-2 shows that the optimal BP targets for people with CKD remains a topic of on-going debate (Kovesdy et al., 2014).

Table 2-2: BP targets for CKD sub-populations as per various evidence-based guidelines

Guideline	CKD criterion	BP target	Level of Evidence
KDIGO (Eknoyan et al., 2013)	With albuminuria <30mg/day	≤140/90mmHg	Level 1B evidence
	With albuminuria >30mg/day	≤130/80mmHg	Level 2D evidence – same recommendation for albuminuria >3000mg/day - level 2C evidence
JNC – VIII (James et al., 2014)	CKD >18 years of age	≤140/90mmHg	Expert opinion Grade E evidence
European Society of Cardiology (Mancia et al., 2013)	CKD > stage 3 CKD 3 with overt proteinuria	≤140/90mmHg ≤130mmHg	Level 2B evidence
Australian CARI guidelines (Heerspink, Ninomiya, Huxley, & Perkovic, 2010)	CKD > stage 3 CKD 3 with macroalbuminuria	≤140/90mmHg ≤130mmHg	Level 2D evidence Level 2B evidence

Abbreviations: KDIGO – Kidney disease improving global objectives, CARI – Caring for Australians with Renal Impairment, JNC-VIII - Eighth Joint National Committee, CKD – Chronic Kidney Disease.

Because of the limited number of randomised controlled trials (RCT), the core recommendations in these guidelines (Table 2-2) are based on modest evidence limited to post hoc analysis following the conclusion of the randomised trial period (Appel et al., 2010; Klahr et al., 1994; Ruggenenti et al., 2005; Sarnak, Greene, & Wang, 2005; Wright et al., 2002).

A recent landmark trial, the Systolic Blood Pressure Intervention Trial (SPRINT) study (SPRINT Research Group, 2015) showed that intensive BP treatment to <120mmHg systole was not more effective than standard treatment to treat SBP <140mmHg in any of the renal outcomes in the established CKD sub-population. However, among those without established CKD at baseline, intensive BP treatment led to a higher incidence of CKD, calculated as a >30% reduction in GFR to <60ml/min/1.73m^2. Although the primary analysis, including non-CKD participants showed a clear, significant improvement in all-cause survival (HR 0.78 [0.67–0.90]) and CVD death (HR 0.57 [0.38–0.85]), it appears that adequate BP control to standard guidelines is sufficient to reduce negative renal and CVD related complications in the established CKD population.

Treatment to achieve BP targets involves a multitude of antihypertensive medications (Unni et al., 2014). First-line medications are angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs) (~80% patients) (Unni et al., 2014). Second line are considered diuretics and beta-adrenergic antagonists (Beta-blockers), which are not effective alone at reducing BP (Unni et al., 2014), yet have been shown in a recent meta-analysis to reduce all-cause mortality (Badve et al., 2011). However, a combination of the above pharmacological agents is used in practice, with less than seventy percent of people with CKD achieving adequate BP control (Razavian et al., 2011; Unni et al., 2014).

As BP control is known to be sub-optimal, other strategies are necessary to assist in the pharmacological management of hypertension in CKD. A strong evidence base supports the renal protective effects of modified dietary sodium in reducing BP (thus controlling hypertension) (Aburto et al., 2013; He, Li, & MacGregor, 2013; McMahon et al., 2015) and improving the pharmacological effect of first line antihypertensive medications (ACE and ARB inhibitors) (Vegter et al., 2012).

2.3 Dietary sodium modification: a key management strategy in CKD

For many years the harmful effects of excessive dietary sodium intake have been argued, predominantly for its effect on BP. From epidemiological evidence, one of the first landmark studies was the International Study on Salt and Blood Pressure (INTERSALT) study. This study found that lowering sodium intake by 100mmol/day reduced SBP by 3-6mmHg and prevented any age-related rise in SBP (Elliott et al., 1996). In a meta-analysis of all dietary sodium RCTs in the general population (non-CKD studies), BP has been decreased by 5.06/2.7mmHg (SBP/DBP) in individuals with hypertension, and -2.03/-1.2mmHg in individuals defined as normotensive (He et al., 2013). Thus, most public health programs now recommend reducing dietary sodium intake regardless of BP status as a preventative measure to the pathogenesis of hypertension.

These findings were used in the development of Australian National Health and Medical Research Council (NHMRC) public health guidelines, which recommend an upper limit of 2300mg sodium (6g salt) per day, and an adequate intake set much lower at 460-920mg sodium (1-2.5g salt) per day (Nutrient Reference values for Australia and New Zealand, 2005). This is in alignment with international guidelines such as the Institute of Medicine (Yaktine, Oria, & Strom, 2013) and the World Health Organisation (WHO) (World Health Organization, 2012). Such guideline recommendations have very poor uptake in the general population though, with estimated intake exceeding 8-12g a day in some westernised societies (He & MacGregor, 2010).

Good quality evidence from RCTs supports the effectiveness of reduced sodium intake in improving a range of outcomes for people with CKD. Aside from increases in BP, cardiovascular morbidity and mortality, high dietary sodium intake is associated with increased proteinuria and accelerated decline in kidney function (Smyth et al., 2014). Dietary management and control of sodium intake is arguably one of the most fundamental treatment strategies for CKD.

The Ramipril Efficacy in Nephropathy (REIN I & II) trials, were RCTs conducted in 1992 and 1999, consisting of 177 patients with proteinuric CKD (REIN I), and 335 patients (REIN II) who were randomised to either control group or to treatment group receiving the ACE inhibitor (Ramipril). Both trials recruited adult participants with CKD and confirmed proteinuria (urinary protein excretion ≥1 g/24 hours for at least three months without urinary tract infection or overt heart failure) (Ruggenenti et al., 1999; Ruggenenti et al., 2005). In a post-hoc analysis conducted by Vegter and colleagues (Vegter et al., 2012), the 500 non-diabetic CKD participants of REIN I & II were categorised according to their average urinary sodium/creatinine excretion: n=111 consuming a low sodium diet (<100mmol/day), n=336 consuming a medium sodium diet (100-200mmol/day), and n=53 consuming a high sodium diet (>200mmol/day) (Vegter et al., 2012). At an average of four year follow up, a higher sodium diet was associated with a 3.3-fold (95%CI 1.7 to 6.4) increased risk of progressing to ESKD compared to a lower sodium diet (p<0.001). This risk remained significant when comparing to the medium sodium diet group (2.4-fold increased risk; 95% CI 1.4 to 4.1; p=0.002) (Vegter et al., 2012). Proteinuria reduced by 31% (p<0.001), and 20% (p=0.036) versus baseline in the low sodium and high sodium diet, respectively. In subsequent follow up, proteinuria had returned to baseline values in the high sodium group, whereas proteinuria reduction was sustained in the low sodium group for the entire follow up period. The use of BP lowering medications was not significantly different among the different levels of sodium intake at baseline. However, on subsequent follow-up there were fewer patients taking diuretic medication in the lower sodium intake group than in the medium and high sodium intake (reduction of 5.5% compared to an increase of 3.8%) (Vegter et al., 2012). Overall, this post-hoc analysis demonstrated a risk of progression to ESKD increases linearly with increasing dietary sodium intake; whereby for each 100mmol/day increase in urinary sodium/creatinine excretion a 1.61-fold (95%CI 1.15 to 2.24) greatest risk for ESKD was observed (Vegter et al., 2012).

Subsequent clinical trials such as the original RENAAL (Brenner et al., 2000) and IDNT (Rodby et al., 2000) support these findings. A post hoc analysis in 1,117 diabetic patients from these trials evaluated the role of dietary sodium intake (as determined by 24-h urine sodium excretion) in conjunction with angiotensin-receptor blockers in preventing CKD and CVD end points.(McMullan et al., 2014) The results showed that patients with the lowest sodium-to-creatinine ratio had the highest reductions in 24-h urinary albumin-to-creatinine ratio and SBP. However, changes were not significant in those with the highest baseline sodium-to-creatinine ratio (McMullan et al., 2014).

2.3.1 The effect of dietary sodium on blood pressure and cardiovascular disease risk

Controlling BP through dietary sodium modification is only important if it translates to a reduction in CVD outcomes. There is uncertainty regarding the relationship between sodium and CVD from the level 1 evidence to date (Taylor, Ashton, Moxham, Hooper, & Ebrahim, 2011). Unfortunately, meta-analyses specifically including RCTs with cardiovascular outcomes (including non-CKD populations) have not been able to determine a risk of CVD, due to the lack of long term clinical trials (Aburto et al., 2013; Adler et al., 2014).

Furthermore, findings from systematic reviews of observational cohort studies (NHMRC level 3 evidence) exploring the association of sodium intake with CVD outcomes are divided and flawed with methodological issues (Cobb et al., 2014). Meta-analyses that have examined the relationship between dietary sodium and CVD/all-cause mortality are tabulated in Table 2-3.

Table 2-3: Systematic reviews examining the relationship between dietary sodium and CVD/all-cause mortality.

Study-*citation*	Intervention characteristics	Δ BP	ACM	CI	CVM	CI	Comment
(Hooper, Bartlett, Smith, & Ebrahim, 2002)	50-100mmol/ day 36 months 11 trials n=3514	-2.31/-1.16 (NT) -8.01 /-4.65 (HT)	**RR 0.90** (n=2393; trials)	0.36 to 2.24	**0.82** (n=748; 2 trials)	0.56 to 1.21	- Meta-analysis of RCTs trials ≥ 6 months f/u data. - Similar studies to *Taylor et al.* - Did not exclude concomitant interventions. - Large changes in untreated HT sub-analysis – some studies also included exercise advice.
(Adler et al., 2014)	70-100mmol/ day >6 months (median NP) 8 trials n=7284	-1.15 /-0.8 (NT) -4.14 /-3.74 (HT)	**RR 0.96** (n=6603; 7 trials)	0.81 to 1.10	**0.67** (n=1981; 1 trial)	0.45 to 1.01	- Meta-analysis of RCTs trials ≥ 6 months duration. - Long-term data for CVD is based on observational data. - In 3 studies compliance measures were discontinued beyond the end of the study so follow-up data may not be truly representative of sodium intake. - High (50%) attrition and risk of follow up bias. - One intervention included increasing potassium in diet. - Included heart failure trials.
(Strazzullo, D'Elia, Kandala, & Cappuccio, 2009)	Sodium intake NP (3.5-19y) 13 trials n=177,025	NP	**RR 1.23 for stoke** (n=5161; 10 trials)	1.08 to 1.43	**1.17** (n=5161; 10 trials)	1.02 to 1.32	- Meta-analysis Prospective observation trials ≥ 3 years. - 12 studies were analysed concerning CVD risk, of which nine showed suggestive trends, and only six provided trends at the significant level. The other three studies, showed inverse relationships.
(Aburto et al., 2013)	Sodium intake NP (4 wk – 36 months) 16 trials n=67998	-3.39 /-1.54	**RR 1.06** (n=215, 151; 7 trials)	0.94 to 1.2	**1.12** (n=464, 831; 9 trials)	0.93 to 1.34	- Meta-analysis RCTs & prospective cohort trials ≥ 1 year. - Included quasi-randomised trials, non-randomised trials, and prospective, observational cohort studies. - Sodium intake/difference not defined. - Excluded trials with no reliable measure of sodium intake, and retrospectively designed trials.
(Mozaffarian et al., 2014)	Sodium intake NP n=1.38 million	1.65 million annual deaths from cardiovascular causes (95% uncertainty interval [confidence interval], 1.10 million to 2.22 million) were attributed to sodium intake above the reference level (2g/day)					- Meta-analysis of cohort studies. - Modelling equations used in this study rely on linear relationships between sodium intake and blood pressure being, and also blood pressure and CVD.

Study-*citation*	Intervention characteristics	Δ BP	ACM	CI	CVM	CI	Comment
(Graudal, Jürgens, Baslund, & Alderman, 2014)	Low sodium versus Usual sodium, verse High sodium 9.9yrs (1-21y) 25 trials n=274,683	NP	**HR 1.16** (n=48131; 11 trials) High V usual sodium	1.03 to 1.30	**1.12** (n=163,101; 11 trials) High V usual sodium	1.02 to 1.24	- Meta-analysis of observation trials with outcomes on ACM. - Healthy and diseased persons, irrespective of race, sex, and age were included. - Analysed by 'Low sodium' (mean daily sodium intake <115 mmol), 'Usual sodium' (mean daily sodium intake of 115–215 mmol), and 'High sodium' (mean daily sodium intake >215 mmol). - 'Usual sodium' further analysed by 'Low usual sodium' (115–165 mmol) and 'High usual sodium' (166–215 mmol). - High verse low sodium, and usual verse low Na+ indicated inverse relationships – however, majority (19 trials) included high risk subjects in sample). - 15 studies had only one measure of sodium intake.

Abbreviations: CI: 95% confidence interval, RR: relative risk, HR: hazard ratio, g: gram, f/u: follow up, ACM: All-cause mortality, CVD: cardiovascular disease, HT: hypertension, NT: normotension, NP: not published, RCTs: randomised controlled trials.

Despite strong linear trends for the control of BP and associated CVD outcomes in the observational literature, inverse or *J-curve* relationships have been documented, which signify higher all-cause mortality at both the highest and lowest intakes of sodium. In recent years, the scientific merit of this J-shapes curve has been scrutinised for its methodological issues and lacking high level evidence (Cobb et al., 2014; Whelton & Appel, 2014). For example, in recent analyses reporting a J-curve relationship (Stolarz-Skrzypek & Staessen, 2015), the authors have included studies with only one measure of sodium intake over many years of follow up; either urinary excretion (24hr/spot/overnight samples) or dietary (recall/questionnaire) (Cobb et al., 2014; Merino et al., 2015). This is a critical limitation to these study designs, and many have questioned whether a true association between all-cause mortality and dietary sodium intake can be interpreted from a single measure of sodium intake. In addition, there are limitations in urinary sodium collections and diurnal variation in daily intake, and dietary recall methods which notoriously underestimate dietary sodium` intake (Beevers, 2002; Whelton et al., 2012). Furthermore, it seems that these relationships may only relate to people at high risk of CVD (Alderman, Madhavan, Cohen, Sealey, & Laragh, 1995; O'donnell et al., 2011; Stolarz-Skrzypek & Staessen, 2015) and are likely subject to reverse-causality, whereby high risk (e.g. heart failure) patients are told to reduce their sodium intake to avoid mortality (thus subsequent mortality would be unrelated to their sodium intake but in-fact their underlying condition) (Merino et al., 2015; Whelton & Appel, 2014). Another possibility is that certain populations may have a reduced sodium intake in the context of malnutrition (i.e. a reduced sodium intake as a consequence of not eating), which would further confound the conclusions that could be drawn.

In contrast to these findings, a recent large scale meta-analysis reported on the results of 107 RCTs (all durations, levels of sodium intake and measure of compliance) (Mozaffarian et al., 2014) showing that for each reduction of 2.3 g of sodium per day, a reduction of 3.8 mmHg (95% CI 3.08 to 4.55) in BP may result. This study postulated that 1.65 million annual deaths from CVD (95% CI 1.10 million to 2.22 million) were attributed to a sodium intake above 100mmol/day. The statistical estimations used by these investigators do have limitations as they rely on linear relationships between sodium and BP. Furthermore, the sodium estimations were based on single morning urine collections, adding further confusion to the literature.

Thus, all observational evidence must be taken in context of their study designs and associated methodological limitations. Given a lack of high level evidence, the evidence for a

J-curve relationship is controversial at best. Furthermore, prior to the year 2016, not one study had been conducted in a CKD population. In a re-analysis of the Chronic Renal Insufficiency Cohort (CRIC) study, Mills et al explored the association between 24-hour urinary sodium excretion and clinical CVD events among 3,757 patients with established CKD (Mills et al., 2016). Over a median follow-up of 6.8 years the highest intake of sodium (>4548mg/24 hours) compared to the lowest (<2894mg/24 hours) was associated to a significantly higher rate of composite CVD outcomes (HR 1.36, 95%CI 1.09 to 1.70) with no evidence of a J-curve. This study is notably limited as it cannot infer causality, however some strengths which surpasses the observational literature in the general population. First, compliance to 24 hour urine collections was high (>80%) and multiple collections were used across the study period, reducing the bias in single 24 hour collections (Powe & Bibbins-Domingo, 2016). Second, the relationship held robust regardless of changes in BP, indicating the mediating factor likely goes beyond that of BP control, and can include arterial stiffness and volume (fluid status) control. This was evident in the strong association to heart failure events for high verses low sodium intake (HR 1.34, 95%CI 1.03 to 1.74).

Despite caution advised against excessive restriction, RCT evidence suggests dietary sodium modification is an important management strategy in CKD. A recent Cochrane review and meta-analysis indicated clear benefits of sodium restriction on BP and BP-independent effects in short-term studies in CKD studies, showing clinically meaningful SBP reductions ranging from 2-12mHg SBP and 1-8mmHg diastolic blood pressure (DBP) in trials one week to six months in duration (McMahon et al., 2015). Meta-analysis showed dietary sodium reduction (MD -105.9, 95%CI -119.2 to -92.5mmol/day) resulted in significant reduction in SBP (MD -8.76, 95%CI -11.35 to -3.80 mm Hg). A summary of RCTs which have tested high against low sodium intake in CKD populations is shown below in Table 2-4.

Table 2-4: Randomised controlled trials of the effect of sodium reduction on blood pressure and kidney function in chronic kidney disease

Study citation	Population	Intervention	Control/ comparators	Duration	Markers of compliance	Outcome	Δ	Comments:
(Ruilope et al., 1992)	CKD (unknown eGFR), essential HTN, n=14	68mmol/day target – 17mmol intake + 51mmol supplement + veraparil Xover	187mmol/day target – 17mmol intake + 170mmol supplement + veraparil	**1 week** intervention with a 4 week run-in	24 hour Na excretion – number not outlined.	**BP**	-1.9/ 0.2 mmHg	- No washout period, very small sample n=14 – potentially explain low BP changes. - Delivery of sodium intervention (i.e. how 1g salt/day was achieved) not described.
(Cianciaruso et al., 1996)	Chronic glomerulonephritis (mean eGFR 41), n=14	Low sodium diet 35mmol/day Xover	Low sodium diet 35mmol/ day + 200mmol sodium tablets	**1 week** intervention	24 hour Na excretion – daily	**MAP**	-8.9 mmHg	- No randomisation or blinding. - Only MAP reported. - Very small sample n=14.
(Konishi et al., 2001)	CKD, IgA nephropathy only (other CKD excluded), n=41	Low salt group – 87mmol/day (controlled feeding) Xover	Control (209mmol/day) – controlled feeding.	**1 week** intervention with a 1 week run-in	24 hour Na excretion – 3 days at end of intervention	**BP** **Protein-uria**	-12/-8 mmHg -742 mg/day	- No washout period. - Divided subjects into tertiles according to baseline BP (normotension, high normal BP, HTN).
(Vogt, Waanders, Boomsma, de Zeeuw, & Navis, 2008)	CKD, non-diabetic, n=34	Placebo plus low salt diet (50mmol/day) – Dietary advice. Xover	Placebo plus regular salt diet (200mmol/day)	**6 week** intervention	24hr Na+ excretion - Baseline and at 2 wk	**BP** **Protein-uria**	-6/-3 mmHg -800 mg/day	- Do defined BP cut off. - Unclear washout b/w treatment groups. - Protein education to maintain intake over study period.

Study citation	Population	Intervention	Control/ comparators	Duration	Markers of compliance	Outcome	Δ	Comments:
(de Brito-Ashurst et al., 2013)	CKD (eGFR <60), BP >130/80mmHg OR HTN on medication, n=56	Tailored low-salt education. Cooking classes and fortnightly phone calls. Traditional recipe's modified 50% less salt. Parallel	Standard care – Received low salt general advice handout.	**6 month** intervention	24hr Na+ excretion - Baseline and at 6 months	**24hr BP** **eGFR**	-8 / -3 mmHg 0.4 mL/min	- Single 24hr collection over 6 months to measure compliance. - 24hr BP only measured at baseline and end of F/U. - Lower protein intake possible explanation for decrease in proteinuria.
(Kwakernaak et al., 2013)	CKD (No eGFR criteria – creatinine clearance >30ml/), non-diabetic nephropathy, BP> 125/75mmHg, n=52	ACE inhibitor + low salt diet *(50mmolNa+/day)* 2-4 dietary counselling sessions to reduce salt Xover	ACE inhibitor with placebo plus regular salt diet *(200mmolNa+/ day)*	**6 week** intervention with a 6 week run-in	24hr Na+ excretion - Baseline and at 3 wk.	**Clinic BP** **Protein-uria**	-11/-7 mmHg -830 mg/day	- Feasible real-life intervention. - Baseline proteinuria not estimable. - Data only extracted from groups 1 & 3. - Concomitant intervention.
(McMahon et al., 2013)	CKD (stage 3,4), BP 130-167/>70mmHg, >18yrs n=20	Low salt group – 60-80mmol/day + placebo Received education from dietitian Xover	Low salt group – 60-80mmol/day + sodium tablets (120mmol/day)	**2 week** intervention with a 1 week run-in	24 hour Na excretion, Mid-stream urine, Diet history, FFQ	**24hr BP** **Protein-uria** **Albumi-nuria** **PWV** **PWA** **eGFR**	-9.7/-3.9 mmHg -342 mg/day -148 mg/day 0.5 m/s 1.7 % 9 mL/min	- Multiple compliance measures. - Small study sample.
(Meuleman et al., 2017)	CKD (eGFR <60)	Coaching to a low sodium diet <2000mg/day – instructed to self-monitor	Usual care (could include dietitian referral if necessary)	**3 months 6 month follow up**	24 hour Na excretion – baseline, 3 and 6	**24hr BP** **Protein-uria**	-2.1/-2.2 mmH -300 mg/day	- Feasible real-life intervention. - 6 month data extracted only.

Study citation	Population	Intervention	Control/ comparators	Duration	Markers of compliance	Outcome	Δ	Comments:
		at least once a week Parallel			months	**eGFR**	2.3 mL/min	- All changes significant at 3 months, only self-efficacy remained significant after 6 months follow up.
(Saran et al., 2017)	CKD stage 3-4, n=58 Xover	Low sodium diet <2000mg/day, behaviour change intervention	Usual care	**4 week** intervention with a 2 week run-in	24 hour Na excretion – baseline and end of intervention	**24hr SBP**	-10.8 mmHg	- Possible learning effect although washout period.

Abbreviations: Xover: cross-over trial, n: number of subjects, BP: blood pressure, CKD: chronic kidney disease, Na+: sodium, hr: hour, g: gram, m/s: millisecond, mg: milligram, kg: kilogram, mmHg: millimetres of mercury, HTN: hypertension, eGFR: estimated glomerular filtration rate, FFQ: food-frequency questionnaire, yrs: years, wk: week, PWV: pulse wave velocity, PWA: pulse wave analysis, MAP: mean arterial pressure.

As shown in Table 2-4, less than half of the studies have durations greater than four weeks, and therefore interpretation is limited due to the inclusion of studies with small sample sizes (median n=32; range 14-56), short duration of follow-up (median six weeks; range one week to six months), and lack of dietary sodium interventions which reflect real-life practice (i.e. a dominance of sodium supplementation studies). In a 2015 Cochrane review, which included eight studies (two in ESKD and six reported in CKD in Table 2-4), a key limitation was that not one included trails had CVD outcome data or all-cause mortality. This is likely attributable to the small sample sizes and absence of long-term duration trials with the longest trial duration in CKD patients only six months. Unfortunately, no trials reporting this data have been conducted to date, which in-part may be due to the difficulty and expense in conducting RCTs with hard clinical endpoints. Without such evidence, the confusion in the literature will continue and proof-of concept studies will not be translated into clinical practise. Accordingly, large-scale RCTs are needed that incorporate multiple measures of dietary sodium intake and compliance, and are of sufficient duration to allow accurate and reliable reporting of CVD events (Aburto et al., 2013; Burnier & Wuerzner, 2014; Hooper et al., 2002; Taylor et al., 2011).

As seen in Table 2-4, there is good evidence from RCTs that sodium reduction can effectively reduce BP and proteinuria. The LowSalt study (McMahon et al., 2013) is the most robust CKD sodium trial to date, demonstrating NHMRC level 2 evidence for substantial reduction in BP, pulse pressure and proteinuria following a low sodium diet. However, the high sodium intake was achieved through sodium supplementation (i.e. sodium tablets), and the study duration was only two weeks which reduces its clinical application (McMahon et al., 2013). The longest study duration to date is a trial conducted in a sample of 48 Bangladeshi immigrants in the United Kingdom (de Brito-Ashurst et al., 2013). Participants were randomised to cooking classes or to a control group for six months. A dietitian assessed the patients and provided low sodium education (in addition to standard care) to the intervention group. In the cooking classes, participants' traditional recipes were cooked and then modified to be 50 percent less salt. Fortnightly telephone calls were utilised to support the health message delivered by the intervention team and dietitian. After six months, urinary sodium excretion decreased by approximately 122mmol/day and approximately 13mmol/day in the intervention and control group, respectively (de Brito-Ashurst et al., 2013). This change in sodium excretion corresponded to a mean SBP reduction of 7mmHg and 1mmHg increase in the intervention and control group, respectively. DBP reduced by 5mmHg and 2mmHg in the intervention and control groups, respectively (de Brito-Ashurst et al., 2013).

This trial demonstrated that culturally targeted and tailored interventions with regular contact by telephone are effective at reducing dietary sodium intake and ultimately reducing BP. Despite there only being two educational interactions with the research team, increasing the frequency of interaction with a healthcare professional to facilitate behaviour change and provide long term monitoring and support to patients was successful in transferring the responsibility of care to the individual and improving their self-efficacy (de Brito-Ashurst et al., 2013). This trial is an example of a study which reflects a real-world intervention, which could be translated into practice.

The most recent low sodium diet trial in CKD comes from a Dutch group (Meuleman et al., 2017), who conducted a three month open-label randomized controlled trial involving 138 adults with CKD, hypertension, and high urinary sodium excretion (≥120 mmol/day; reflecting higher habitual intake of salt compared to national guidelines). Participants either received fortnightly advice to improve their self-monitoring of sodium (<100mmol/day) and BP control, or usual care according to national best-practice guidelines. The dietary intervention was reflective of dietary education provided in clinical practice. After three months, participants in the self-management intervention led significant decreases in 24-hour urinary sodium excretion and BP, as well as in the secondary outcomes of proteinuria and body weight. This was matched with improved levels of self-efficacy and intervention acceptance. However, at six months (three months post intervention) the sodium results were no longer significant. Even though self-efficacy and BP remained significantly lower than the control group at 6 months, the immediate intervention decay highlights the need for behaviour change interventions which can provide long term monitoring and feedback for complex dietary changes.

In summary, the current evidence-base for dietary sodium restriction in CKD is supported primarily through proof-of-concept studies. Longer term studies have methodological flaws and show conflicting results for their associations with long term CKD outcomes. It seems that dietary interventions that are translatable and pragmatic in clinical practice do show efficacy, however they are more complex, requiring higher levels of support and frequency of contact to achieve the desired dietary change.

2.4 Complexity of diet change

Dietary interventions are exceptionally challenging to practically implement in practice, particularly for those with a chronic disease. Dietary recommendations can be influenced according to the stage of someone's disease, their current treatment, and the best practise guidelines. Furthermore, food selection is heavily influenced by considerable physiological, social and emotional determinants (Brownell & Cohen, 1995; Vanstone et al., 2013). To sustain dietary behaviour change, regular contact with health professionals and long-term follow-up is essential (Renders et al., 2001). The complexity to dietary change is further exacerbated in interventions such as reducing dietary sodium intake, because the magnitude of dietary monitoring changes required can severely impact on the success and compliance of the program (Smyth et al., 2014). In CKD and dialysis patients specifically, the suite of lifestyle and medical management strategies are incredibly intensive (Bonner et al., 2014) and dietary changes are complex and not solely focused on a singular dietary component (Smyth et al., 2014).

A recent qualitative synthesis summarised the experiences of CKD and dialysis patients when implementing diet and fluid recommendations (Palmer et al., 2014). It included 46 studies and showed that kidney patients experience conflict in dietary advice and feel an intense burden when trying to adopt these into their everyday life. People with kidney disease described feeling 'overwhelmed by information' and that too much (complex) information is given in 'one-off education sessions'. To overcome these challenges, patients expressed preference for a collaborative approach to learning in partnership with dietitians and their families. Additionally, patients desired regular coaching and monitoring to help them understand dietary information and become confident in their ability to self-monitor and manage these changes (Palmer et al., 2014). This type of approach is known to improve their dietary adherence (Bonner et al., 2014), and such strategies are central to successful change in dietary behaviour.

2.4.1 Addressing the complexity: a move toward dietary patterns

Adding to this complexity, dietary recommendations for those with a diet-related chronic disease usually reflect singular nutrients, and not whole foods. The 2013 Australian Dietary Guidelines were published, reflecting an emphasis on whole foods, rather than specific nutrients. This was because previous fascination and focus on individual nutrients was known to cause dietary confusion and to impede the maintenance of behaviour change (Australian

Institute of Health and Welfare, Cat. no. AUS 178; National Health and Medical Research Council, 2013).

Interventions aimed at changing whole dietary patterns are well documented throughout the literature. Since 1983 a range of patterns have been trialled (Howard et al., 2006; Hutchison et al., 1983; Takahashi, Sasaki, Okubo, Hayashi, & Tsugane, 2006), with the most recent substantial body of literature relating to Mediterranean-type and the Dietary Approaches to Stop Hypertension (DASH) dietary patterns (Athyros et al., 2011; Esposito et al., 2004; Estruch et al., 2013; Singh et al., 2002; Wardle et al., 2000). These studies typically include intensive education periods with participants, usually provided by regular individual and/or group sessions. Most of the landmark dietary pattern studies thus utilise controlled feeding study designs (Appel et al., 1997; Appel et al., 2005; Blumenthal et al., 2010; Sacks et al., 2001; Writing Group of the PREMIER Collaborative Research Group, 2003), which do not reflect true behaviour change interventions. For these reasons, these studies are considered proof-of-concept and are not translatable into practice.

Controlled feeding studies, despite translational limitations, provide high quality (and highly controlled) evidence for the effect of dietary patterns in controlling BP. Originating some 30 years ago, a series of studies were conducted in vegetarians (who were observed to have lower BP than animal protein consumers) (Sacks & Kass, 1988). In these studies, changing specific micro and/or macro nutrients did not alter BP, leaving the authors to conclude it likely that BP is affected by a series of nutrients from within the dietary pattern. These findings led to originated subsequent food-based dietary pattern research, such as the DASH trial which demonstrated the efficacy of the DASH dietary pattern for the control of BP.

The DASH-sodium study was the first clinical trial to explore a concept of dietary patterns over targeted nutrients with an emphasis on dietary sodium (Appel et al., 1997; Sacks et al., 1995; Sacks et al., 2001). The DASH sodium showed a combined effect of a DASH pattern and low sodium diet to reduce SBP by 11.5mmHg in hypertensive subjects and 7.1mmHg in pre-hypertensive subjects. Following the results of these original DASH pattern trials, subsequent trials have utilised this dietary pattern for the control of BP and other clinical outcomes. These trials have been reviewed, providing level I evidence on the effects of the DASH pattern on BP (Saneei, Salehi-Abargouei, Esmaillzadeh, & Azadbakht, 2014). In a meta-analysis of all available 17 studies, involving 2561 participants, the overall effect size of DASH pattern reduced SBP by 6.7 mmHg (95%CI -8.3 to -5.2) and DBP by -3.5 mmHg

(95%CI -4.3 to - 2.8). Intervention strategies included the provision of DASH pattern dietary advice in 12 RCTs, whilst the remaining five RCTs were controlled feeding conditions (full/partial food provision). The other major variation in the interventions was energy restriction, with eight studies encompassing energy restriction and eight others not (one study used both in a three-arm trial). Studies with concurrent energy restriction reduced SBP more substantially (MD-8.13, 95% CI -10.75 to-5.31];p<0.001) than studies that did not (MD-5.57, 95% CI -7.43 to -3.7;p<0.001).

The recommended nutrient intakes advised for people with CKD are mostly in-line with Australian Dietary Guideline recommendations, with relatively minor modifications for non-dairy alternatives lower in calcium and low potassium fruit/vegetables if required. While the DASH and Mediterranean patterns are higher protein (as a percent of total calories consumed), they contain higher plant-based protein ratios which may be kidney-sparing and cardio-renal protective (Kidney Disease Outcomes Quality Initiative (K/DOQI), 2004). The bioavailability of phosphorous and calcium from plant-based sources is typically poor which strengthens the kidney-sparing potential these diets may possess (Moe et al., 2011). The nutrient differences in the common dietary patterns is summarised in Table 2-5.

Table 2-5: Average nutrient content of the DASH, Mediterranean and ADG diets

Nutrient	MED^	DASH#	AHA¥	ADG+	CKD diet*	Dialysis*
Protein (%EEI)	10-19	18	15	10-35	10	15-18
Fat (%EEI)	20-30	27	<30	20-35	<30	<30
Saturated (%EEI)	10	7	<10	<10	<7	<7
Monounsaturated fat (%EEI)	15	10	>30 combined¥	11	>20	>20
Polyunsaturated fat (%EEI)	5	7		NR	>10	>10
Carbohydrates (%EEI)	45-70	58	<60	45-65	50-60	50-55
Fibre (g/day)	37	30	>25	20-30	20-30	20-30
Sodium (mg/day)	3616	2886	<2400	<2300	<2400	<2400
Potassium (mg/day)	6132	4589	NR	4700	2000-4000	2000-4000
Phosphorous (mg/day)	2226	1481		700	800-1000	
Calcium (mg/day)	1409	1220		1000-1200	700	

Abbreviations: ADG: Australian Dietary Guidelines, MED: Mediterranean, EEI: Estimated Energy Intake; g: gram; mg: milligram; NR: No recommendation. ^ Reference: (Almeida, Parisi, & Delgado, 2017; Serra-Majem et al., 2009), # reference: (Karanja et al., 1999), ¥ reference: (Lichtenstein et al., 2006), + reference: (National Health and Medical Research Council, 2013), *As recommended by the K/DOQI guidelines. ¥ >30% energy from Mono- and poly-unsaturated fatty acids combined.

As shown in Table 2-5, there are differences in the nutrient content of these common dietary patterns, which might not always be appropriate for the CKD patient. Commentary articles have outlined that the DASH pattern has important concepts that are potentially valuable for the management of CKD (Thoms, 2004) and dialysis patients with some slight modifications (Lindley, 2009). The DASH eating pattern is endorsed by the National Heart Foundation and is recommended for management of hypertension and prehypertension (Huang, Duggan, & Harman, 2008). The Kidney Health Australia CARI and the 2004 KDOQI guidelines deem the DASH pattern in early CKD a suitable method to increase fruit and vegetable intake and improve kidney outcomes (Chan & Johnson, 2013; K/DOQI working group, 2004), however note the typically high intake of protein (1.4g/kg/day) and advise caution in the absence of clinical trials (Chan & Johnson, 2013). The 2007 KDOQI guidelines on nutrition in diabetes and CKD allude to a ‘DASH-type’ diet which concludes protein intake as likely safe, given an altered red meat-to-plant-based protein ratio as potentially ‘kidney sparing’ (National Kidney Foundation, 2007). It is not known whether the type of protein or the macro/micronutrient profile of this dietary pattern is the influential contributor to this effect, however. Overall, the weight of available evidence and guideline recommendations suggests that the DASH pattern and other similar dietary patterns may be modifiable to be suitable and beneficial to CKD patients.

With an absence of clinical trials for a DASH pattern in CKD, a recent five week single arm (non-randomised) trial on the feasibility of using the DASH pattern (maintaining protein intake 1g/kg/day, 1500g sodium/day) was conducted to assess safety in people with stage 3 CKD patients and co-morbid hypertension (Wells, Hannah, & Jones, 2015). After a one-week run-in period, participants had regular blood tests for safety monitoring of blood biochemistry. The primary outcome measures were blood and urinary electrolytes with secondary outcomes being changes in clinic BP, other nutrients, and overall acceptability of the DASH pattern. The DASH pattern intervention proved to be safe in all participants, with one participant withdrawal during run-in due to a serum potassium of >5.5mmol/L, unrelated to the intervention. Mean dietary sodium was reduced from 2785mg to 1583mg per day ($P< 0.001$). Importantly, serum potassium and dietary potassium and protein intake did not significantly change throughout the five-week study period. However, a trend in urinary potassium bordered on significance after increasing from 77mmol/L to 85mmol/L (p=0.051) suggesting that participants were able to effectively regulate the slight increase in dietary potassium intake. A small single arm study (Tyson et al., 2016) has also supported the safety of a two week DASH pattern on BP and serum biochemistry in CKD. No incident hyperkalaemia was observed, and there were no significant changes to ambulatory or clinic BP after 2 weeks (Tyson et al., 2016). The results of this trial, as with the previous safety trial, contest arguments against a DASH-like pattern in CKD. However, without a control group, the reduction in urinary sodium and BP achieved should be interpreted with caution. Other important limitations to this study include the lack of a diet quality outcome and no measures to monitor the effect on sustaining behaviour change. However, the findings support the acute safety of a DASH pattern in CKD and support the notion that increasing fruits and vegetables may be achievable with minimal risk to incident hyperkalaemia.

Similarly, the evidence for the Mediterranean diet suggests it is likely a safe intervention for CKD populations. Unlike the DASH pattern, however, there is no one standardised Mediterranean diet. Rather, the widely used term Mediterranean diet reflects a variety of eating habits traditionally practiced by populations in countries bordering the Mediterranean Sea, with considerable variability by location. The Mediterranean diets is rich in healthy food groups, such as fruits, vegetables, legumes, fibre and lower in red- and processed meats. In addition, this dietary pattern is inherently lower in sodium and saturated fat, and higher in potassium, unsaturated fats, and polyphenols (Davis, Bryan, Hodgson, & Murphy, 2015). The Mediterranean diet has well established associations with reduced CVD incidence and mortality in the non-CKD population (Estruch et al., 2013; Rees et al., 2013; Sofi, Cesari, Abbate, Gensini, & Casini, 2008; Trichopoulou, Bamia, & Trichopoulos, 2009). Long term outcomes have not been tested in CKD clinical trials, however one cohort study estimated that dietary improvements by two-points on the Mediterranean diet score translated to a reduced risk of all-cause mortality (HR 0.77, 95% CI 0.63 to 0.93) (Huang et al., 2013). One known trial has demonstrated the Mediterranean diet's effectiveness in reducing systemic inflammation and microalbuminuria (De Lorenzo et al., 2010), which further supports that a healthy dietary pattern may translate to better clinical outcomes in the CKD population.

Healthy dietary patterns promote higher plant-based food intake, and less refined and processed food. Fundamentally, healthy dietary patterns may contribute to improved clinical outcomes in CKD due to being higher in fruit and vegetables (with vitamins and antioxidants) (Wai, Kelly, Johnson, & Campbell, 2016a), fish and omega-3 fatty acids (Chrysohoou et al., 2013), legumes, wholegrain cereals and nuts (Gutiérrez et al., 2014; White, 2017), and at the same time promoting a lower consumption of sodium (McMahon et al., 2015), red and processed meat (Lew et al., 2016), saturated fats (Lin et al., 2010), and common phosphate additives that are highly prevalent in the Australian food supply (McCutcheon, Campbell, Ferguson, Day, & Rossi, 2015). Adopting a healthy dietary pattern in CKD is consistent with the dietary advice given in healthy eating guidelines to the general population (McGuire, 2016; National Health and Medical Research Council, 2013). While the DASH and Mediterranean diets do have evidence for effectiveness in reducing CVD risk in non-CKD populations (Saneei et al., 2014; Schwingshackl & Hoffmann, 2014), this evidence is limited in CKD (Tyson, Nwankwo, Lin, & Svetkey, 2012). It is possible that aligning CKD diet guidelines with that of the Australian Dietary Guidelines better represent a pragmatic strategy to improve diet quality, increase plant-animal protein ratio, minimise sodium intake, and ultimately improve short- and long-term clinical outcomes. However, the Australian Dietary Guidelines, as a dietary pattern, remains an untested intervention strategy in the CKD population. It is also largely unknown what amount of individual support would be required for people with CKD to adopt this dietary pattern, and whether the current healthcare system has the resources to meet these demands.

In summary, dietary patterns reflect a whole pattern of eating and have widely accepted evidence for reducing BP and cardiovascular health. Evidence of potential effectiveness likely relates to the synergistic effects of all the foods and nutrients as part of the dietary pattern. As dietary patterns are a whole food-based intervention and characteristically higher in fruit, vegetables and wholegrains, caution has been advised in the CKD population due to potential electrolyte derangement. It is important to note that there have been no randomised controlled trials conducted to either support or refute these claims and so potential harms from higher fruit and vegetable intake in CKD populations remains unclear. Preliminary data shows there are no adverse effects from following a DASH pattern in CKD. Promoting fruit, vegetable and wholegrain intake in-line with the Australian Dietary Guidelines represent a healthy dietary pattern which is in-line with current renal practice guidelines. Although this intervention may be promising to test in the CKD population, it is unclear how clinicians can best support people with CKD adopt and adhere to these complex dietary changes in a safe manner.

2.5 Healthcare challenges to improving dietary behaviour change

Regular contact with health professionals and repeated follow-up is required to sustain long-term dietary behaviour change (Renders et al., 2001). Dietary change is but one component of the suite of lifestyle and medical management therapies in CKD, which as described previously are incredibly intensive and difficult to implement (Bonner et al., 2014).

The growing prevalence of CKD in Australia (Campbell & Murray, 2013) and globally (Baek et al., 2012), paired with the persistent rise in diet-related chronic disease, has led to increasing demand on health services and resources (Wilcox, 2014). One of the consequences, across major renal services in Australia, has been that specialised renal dietitians are not always available to care for people with CKD, and there can be inconsistencies in treating practitioners when following up with patients in practice (Campbell & Murray, 2013). At the same time, people with CKD have expressed a preference for regular coaching and monitoring of dietary change (Palmer et al., 2014). However, this is not considered universally feasible in the current models of healthcare.

Dietary education programs are traditionally delivered face-to-face and are limited in their translation to practice due to common logistical constraints. Existing hospital and community-based services available within or outside major metropolitan areas are only attended by a minority of patients, and a large number of patients not willing or unable to travel to face-to-face clinics (Dale et al., 2014; Whelan et al., 2016). Evidence-based recommendations for optimising adherence to dietary recommendations includes the provision of on-going monitoring, coaching and frequent feedback (Desroches et al., 2013).

Dietary interventions which have lower adherence have typically incorporated 'intensive', and 'maintenance' periods of contact to facilitate greater uptake in non-CKD populations (Applegate et al., 1992; Beard, Gray, Cooke, & Barge, 1982; Hypertension Prevention Trial Research Group, 1990; Trials of Hypertension Prevention Collaborative Research Group, 1997; Whelton et al., 1998; Whelton et al., 1997; Writing Group of the PREMIER Collaborative Research Group, 2003). Strategies trialled in the literature include weekly-to-fortnightly group and/or individual sessions with a dietitian, who works with participants to individualise advice to reduce dietary sodium intake and increase adherence to a healthy dietary pattern. These behavioural interventions have typically only shown small reductions in urinary sodium excretion, with compliance declining considerably with reduced contact during maintenance stages and at follow-up (Burke et al., 2005; Hinderliter et al., 2014;

Hypertension Prevention Trial Research Group, 1990; Writing Group of the PREMIER Collaborative Research Group, 2003). The results of these behaviour change interventions suggest that the establishment of long-term behaviour change requires strategies that maintain regular follow-up prevent intervention decay. However, such strategies are not practical at a scale within the current health system. Thus, alternate methods of healthcare delivery may be appropriate, to complement and/or replace traditional dietary intervention delivery.

2.6 Telehealth strategies to address these barriers and improve dietary change

Technology to deliver healthcare interventions is a potential solution to overcome the challenges of face-to-face delivered care (World Health Organization, 2010). Around the world technology is the fastest growing avenue for delivering health interventions. Telecommunications technology use has rapidly grown in recent years and more than three-quarters of the world's population having access to a mobile phone (Shin, 2014). Smart phone and home internet use is currently over 75% in the Australian population (Australian Communications and Media Authority, 2013; Mackay, 2012), which highlights the widespread potential technology has to provide healthcare services. However, the overall effectiveness of technology-based interventions has been debated for over 20 years (Wootton, 2012), and there is little information available about the proportion of the CKD population that use various technologies.

2.6.1 What is telehealth?

Telehealth is an umbrella term that encompasses a whole range of technology-assisted health practice activities, specifically delivered from a distance. There have been numerous studies conducted utilising various telehealth strategies, targeted at various patient populations and delivered by various healthcare professionals (Wootton, 2012). The overall effectiveness of telehealth to date has not been conclusive or consistent (Wootton, 2012), despite more than 22 systematic reviews of chronic disease management via telehealth (Wootton, 2012). The number of telehealth reviews has been so great that meta-reviews (reviews of systematic reviews) have also been conducted and published (Ekeland, Bowes, & Flottorp, 2010; Salisbury et al., 2015; Wootton, 2012). In a meta-review of 80 systematic reviews on telehealth, with no restriction of disease state or health status, of 20 (25%) reviews were identified which concluded telehealth is 'effective', 19 (24%) as 'promising', and 22 (28%) with 'limited and inconsistent' findings (Ekeland et al., 2010). Effective telehealth interventions ranged from home tele-monitoring of heart failure patients, to cognitive behaviour therapy delivered by psychologists. Promising telehealth interventions were mostly targeted towards behaviour or education, with more research needed before reliable conclusions could be drawn. In contrast, the limited and inconclusive telehealth interventions were mostly in emerging technologies (e.g. virtual reality) and self-monitoring data in heart failure. This meta-review highlighted that inconclusive evidence does not equate to in-effective, rather that more research is needed before conclusions can be drawn (Ekeland et al., 2010).

Despite the number of telehealth interventions conducted in chronic disease, the effectiveness for these interventions to influence behaviour change is largely unknown. A recent review constructed a conceptual model for telehealth programs addressing the ineffectiveness of various telehealth interventions among people with a chronic disease (Salisbury et al., 2015). The review concluded that self-monitoring, regular review, and the use of evidenced-based behaviour change programs (e.g. dietary or physical activity) are required to improve chronic disease self-management. A conceptual model for telehealth programs in chronic disease focused on a number of relevant predisposing, enabling, and reinforcing factors that affect patient uptake of a telehealth program has been proposed (see Table 2-6). This work illustrates that patient confidence in the proposed technology, ease of access and simplicity of use, with regular review and encouragement is paramount to the success of the program and study retention.

Table 2-6: Precede-proceed model of factors proposed to influence telehealth use by patients. Adapted from (Salisbury et al., 2015)

Predisposing	‣ Attraction of having support for health problems on demand, having more time, and getting greater support ‣ Patients having a clear understanding of why they have been offered telehealth treatment ‣ Confidence in ability to use the technology ‣ Being reassured about privacy and confidentiality
Enabling	‣ Good access to fast reliable internet connection ‣ Technology which is simple, inexpensive, and not complicated to use
Reinforcing	‣ Benefits of having regular review ‣ Importance of self-monitoring which promotes continued engagement ‣ Encouraging patient activation and involvement rather than passive reminders

Behavioural interventions have also been synthesised in telehealth meta-reviews with varying results. In a recent meta-review of 53 systematic reviews, 232 telehealth-delivered interventions to support five selected chronic disease self-management were evaluated (Hanlon et al., 2017). Overall, the included studies were all complex interventions with multiple components, and therefore no single self-management component was found to be consistently effective. The most commonly utilised tool for behaviour change in the telehealth interventions was 'monitoring and feedback', and this was associated with improved clinical outcomes in diabetes and heart failure. Telehealth was also beneficial for improving 'remote clinical review' and providing 'education and information' in diabetes, cancer and heart failure. However, findings for asthma and COPD were mostly neutral or inconsistent across these components (Hanlon et al., 2017).

Telehealth strategies may provide a feasible way to facilitate dietary behaviour change, and offers a potential solution to overcome many patient-centred-barriers to accessing face-to-face clinics (Goode, Reeves, & Eakin, 2012). Telehealth interventions can provide people with a chronic disease greater flexibility in receiving health services (White, Krousel-Wood, & Mather, 2001), increase the reach of service, the amount of contact a health professional can have with a patient, and have a high rate of acceptability by patients (Bennett, Broome, Schwab-Pilley, & Gilmore, 2011; Deitz, Cook, Hersch, & Leaf, 2014; Nundy et al., 2013; Southard, Southard, & Nuckolls, 2003; Yehle, Chen, Plake, Yi, & Mobley, 2012). The benefits that telehealth offers to patients are often contrasted against conventional programs (Nolan, Liu, & Payne, 2014), as summarised in Table 2-7. These novel approaches can be forecast to reduce overall participant burden (thus enhancing intervention compliance), which hypothetically could facilitate dietary behaviour change. As one example, a person with a chronic disease who may have limited time to attend face-to-face education, may find a telehealth program can provide access to tailored education material without requiring a physical appointment (Dale et al., 2014; Lutz et al., 2014), thus allowing that person to access relevant information from the comfort of their own home, at a time of their own choosing (Southard et al., 2003). Mobile and other telecommunication technologies offer the opportunity to deliver a patient-centred program in a way that both causes minimal disruption to people's lives and improves appointment attendance - commonly observed to be poor in both hospital and community-based health programs (Dale et al., 2014).

Table 2-7: Summary of outcomes and benefits of telehealth in comparison to conventional face-to-face programs; adapted from (Nolan et al., 2014).

Patient Centred Barriers	Conventional Programs	Telehealth
Patient education	✓	✓
Self-monitoring	✓	✓
Provision of feedback	✓	✓
Regular, scheduled		✓
Evidenced-based	✓	✓
Access to on-going health professional communication		✓
Education based on setting and resources		✓
Flexible to daily schedule		✓
Healthcare Barriers	**Conventional Programs**	**Telehealth**
Decrease non-attendance and wasted clinic resources		✓
No waiting time (waiting room)		✓
Overcome parking and logistical challenges		✓
Physician onsite availability	✓	

2.6.2 The effectiveness of telehealth interventions: evidence from systematic reviews

There has been no systematic evaluation of the effects of telehealth for improving complex dietary change in chronic disease. However, several systematic reviews have been conducted in various health conditions and populations, all with varying methodologies and outcomes (including dietary outcomes).

In developed countries, text messaging interventions show promise for improving adherence to clinics and better medication adherence in chronic disease (Beratarrechea et al., 2014). Two reviews have demonstrated that the self-care activities for diabetes control (measured by HbA1c) can be achieved through telehealth (Cassimatis & Kavanagh, 2012), and dietary change may be possible through the provision of internet-based education (Cotter, Durant, Agne, & Cherrington, 2014). However, the evidence is not strong and both reviews did not specifically summarise the dietary outcomes, so interpretation of dietary effectiveness is difficult (Cassimatis & Kavanagh, 2012; Cotter et al., 2014). Two Cochrane reviews report on behavioural outcomes in diabetes (Pal et al., 2013) and in chronic disease (Murray, Burns, See, Lai, & Nazareth, 2005). In a computer-based intervention review to assess effectiveness for the management of diabetes, HbA1c and dietary outcomes showed improvement favouring the intervention for estimated daily fat intake (MD -3.44, 95% CI -7.93 to 1.05) and weekly calorie intake (SMD -0.23, 95% CI -0.46 to 0.01) (Pal et al., 2013). In the other review, web-based computer programs in chronic disease showed an increase in knowledge and self-efficacy was found, and a pooled odds ratio of 1.66 (95% CI 0.71 to 3.87) for all behavioural outcomes (Murray et al., 2005).

The effectiveness of mobile health m-Health interventions has been extensively synthesised. In a recent publication, a compelling narrative review of current m-Health interventions for improving CVD outcomes was conducted (Burke et al., 2015). A total of 69 m-Health studies were reviewed for their effect on CVD risk behaviours, which included 10 RCTs targeting weight loss, 14 on increasing physical activity, 14 aiming to improve smoking cessation, 15 on blood glucose management, 13 on hypertension management, and three targeting lipid management. M-Health facilitated significant weight loss (-0.5 to -6.5kg), as shown by seven of ten studies reviewed, however an emphasis on text message interventions and high rates of attrition (up to 50%) were acknowledged as limitations in the generalisability and translation of this work. In the 15 diabetes studies, HbA1c was the most common outcome measure, as the gold standard measure of glycaemic control with similar outcomes as reported in the previous paragraph. This review found that text message studies had poor retention whereas email interventions generally had high retention in studies on hypertension. Change in SBP ranged from -4.4 to -23.7mmHg (Burke et al., 2015). Important recommendations on study design were made given the poor methodological rigor of the reviewed studies. For example, the majority of studies on physical activity and BP control failed to perform intent to treat analyses, which can potentially introduce bias into the results of these studies. Furthermore, the majority of studies (except for weight loss studies) were short term, thus limiting any conclusions on sustained behaviour change.

Of the evidence available to date, there is clear potential that telehealth technologies can facilitate lifestyle modification, even in the context of their limitations. The current body of telehealth literature is summarised in Table 2-8, showing general support for the use of various telehealth methods in chronic disease. However, these reviews have not analysed dietary change individually (thus not all dietary results are summarised and/or reported), focus on singular telehealth interventions (e.g. telephone only), focus solely on single disease-states and/or they include short-term interventions, which are insufficient to assess sustainable dietary change. In-fact at least two of these drawbacks is present in all telehealth reviews, outlined in Table 2-8.

Table 2-8: Systematic Reviews of relevant lifestyle interventions considering the effect on changing dietary intake

Study citation	Population	Intervention*	Results	Comment on dietary intake
(de Jongh, Gurol-Urganci, Vodopivec-Jamsek, Car, & Atun, 2012)	• General population (primary and/or secondary care, no setting restriction) • Adults • n=182	Mobile n=4	1. HbA1c: (MD -0.15, 95% CI -0.77 to 0.47). 2. Blood pressure: SBP (MD 1.10, 95% CI -4.37 to 6.57); DBP (MD 1.84, 95% CI -2.14 to 5.82). 3. Capacity to self-manage: 5/6 studies showed improvements. 4. Health service utilisation: 2/3 studies: (RR 0.32, 95%CI 0.09 to 1.08).	No dietary outcomes
(Vodopivec-Jamsek, de Jongh, Gurol-Urganci, Atun, & Car, 2012)	• General population • Includes children • n=1933	Mobile n=4	1. Higher satisfaction in the 1 study involving pregnant women. 2. 1 study relating to smoking cessation past 6 months (RR 2.20, 95% CI 1.79 to 2.70). 3. 1 study relating to vitamin C adherence: (RR 1.41, 95% CI 1.14 to 1.74). 4. None of the studies reported the secondary outcomes of health service utilisation or costs of the intervention.	No dietary outcomes
(Currell, Urquhart, Wainwright, & Lewis, 2000)	• General population (direct patient care) • n=800	Telemedicine n=7	1. All measurable outcomes of care for patients treated remotely via telemedicine compared with those treated face-to-face – showed no clear evidence of benefit.	No dietary outcomes

Study citation	Population	Intervention*	Results	Comment on dietary intake
(Aneni et al., 2014)	• General population • Adults • n=NP	Internet n=29	1. Significant weight and WC reduction in the high quality studies. Low quality studies: Weight reductions ranging 0.8-1.4kg for weight and 2.0 – 2.9 cm for waist circumference. 2. High quality studies showed no effect on BP, 3 low quality studies showed a decline in BP. 3. Decline in BGL (1 high quality study), mixed results in poor quality studies. 4. 6 high quality lipid studies – 3 showed reductions in the intervention group. 3 studies that were low quality all showed reductions. 5. Diet – 9 high quality studies. 5 found no improvement. 3 low quality follow-up studies showed improvements in fruit and vegetable intake. 6. PAL – 9 high quality studies only 1 showed significant improvement. 2 low quality studies showed increase in PAL. 7. Smoking cessation: 3 follow up studies showed improvements in smoking cessation.	No dietary outcomes
(Kodama et al., 2012)	• Overweight/obese (only three exclusive obesity studies included) • n=8697	Internet n=23	1. Weight loss: (MD -0.68 kg, 95% CI -1.29 to -0.08).	No dietary outcomes

Study citation	Population	Intervention*	Results	Comment on dietary intake
(Bacigalupo et al., 2013)	• Overweight/obese (only 2 obesity studies included) • n=584 (participants included in quantitative synthesis)	Mobile n=7	1. Weight loss observed in 6 of 7 included studies. 2. 5 studies had clinically significant weight loss compared to the control group.	No dietary outcomes Only one study had a low risk of bias.
(Burke et al., 2015)	• At risk CVD • n=NP	M-health n=102	1. Weight management: Seven of the 10 RCTs, reported significantly more weight loss in the intervention group than in the control or comparison group, ranging from -0.5 to -6.5kg, with pooled effects being -2.56 kg (95% CI -3.46 to-1.65). 2. Physical activity: 9/14 studies report significant improvements on PAL. 3. HbA1c: Pooled effect −0.5 (95% CI −0.3 to −0.7). 4. Blood pressure: Change in SBP ranged from -4.4 to -23.7mmHg, with an systematic review of internet and email studies with at least 8 weeks follow-up finding a pooled MD of -3.8 (95% CI -5.63 to -2.06).	No dietary outcomes The variety of physical activity outcome measures makes synthesis difficult to report it as an outcome.

Abbreviations: HbA1c: Glycated haemoglobin, PAL: Physical Activity Level, CI: Confidence Interval, Kg: Kilograms, BMI: Body Mass Index, WC: waist circumference, SBP: Systolic Blood Pressure, DBP: Diastolic Blood Pressure, MD: Mean Difference, RR: Risk ratio, RCT: randomised controlled trial, NP – not published. BGL, blood glucose level. * Intervention description: Mobile, use of text-messaging using a mobile phone; Internet: online education using secure portals and/or email; M-health: multiple forms of mobile technology (including text-messaging, Apps and tablets).

Perhaps the most relevant systematic review related to dietary change in chronic disease is a Cochrane review (Desroches et al., 2013) that assessed the effectiveness of various methods for enhancing adherence to dietary interventions. This review suggested that improvements to dietary adherence can be facilitated by the use of some technology such as telephone interventions and video contact, but also included face-to-face approaches (Desroches et al., 2013). Although an extensive review, this work was not designed to assess the effectiveness of dietary education in chronic disease, due to the inclusions definition of 'reference standard of care'. Study groups had to be receiving the same dietary advice as the intervention arm, with the comparator being an alternate delivery method for the same dietary advice. Consequently, studies that conducted interventions educating patients about diet that was not provided to a control group (e.g. standard care dietary advice from a dietitian or treating physician), was excluded. From a telehealth potential perspective, this review did not evaluate the effects of telehealth exclusively, and no meta-analysis was conducted due to the high heterogeneity of the studies clinically and statistically. Therefore, the dietary intake and clinical effectiveness of telehealth-delivered dietary interventions in chronic disease management is currently unknown in comparison to standard care.

2.6.3 Telehealth interventions in kidney disease

There are limited trials that have evaluated the effectiveness of telehealth interventions in kidney disease populations. Following a systematic search for all telehealth interventions in chronic disease using a structured search strategy and selection of studies (described in Appendix B), only three trials were found to have been conducted in kidney disease (Cummings, Becker, Kirscht, & Levin, 1981; Williams, Manias, Walker, & Gorelik, 2012; Wong, Chow, & Chan, 2010) (two in ESKD and one in CKD) that met the inclusion criteria in Appendix B.

In a RCT of people with CKD and co-morbid diabetes, the effects of an intervention utilising digital video disk (DVD) education package with fortnightly telephone coaching specifically for medication adherence and self-monitored BP was evaluated. Outcomes were compared to those receiving usual care (Williams et al., 2012). The telephone coaching group effectively lowered the primary outcome SBP by 6.9mmHg compared to -3mmHg in the control, however no significant difference was observed in medication adherence within or between the study groups. This study did not provide dietary coaching, although >50% self-reported at baseline that they managed their diet "well', however, no results were reported at follow-up.

In another RCT, the effect of a telephone-based, nurse-led program was evaluated in patients receiving continuous ambulatory peritoneal dialysis (CAPD) (Wong et al., 2010). In this study, intervention participants were telephoned every week over a period of six weeks by nurse case managers, who provided feedback on patient-goals set in an initial assessment, and then continued to monitor progress and provide health advice (Wong et al., 2010). Participants in the control group received usual care only. Diet and fluid adherence was assessed using the dialysis diet and fluid non-adherence questionnaire (Vlaminck, Maes, Jacobs, Reyntjens, & Evers, 2001) and both groups had improvements in the frequency of days that their diet was adherent to recommended guidelines. However, no significant between group difference was noted. There was a significant between group difference in the degree of dietary adherence (F = 4.19 (p=0.04)). No significant difference between groups was noted for biochemistry and symptom control, however all readings were within acceptable range. Due to the short 6-week follow up, it appears the marginal changes in dietary outcomes were not great enough to alter biochemistry markers. Despite the authors discussing the results as adding to the evidence for CKD, this study was in-fact exclusive to ESKD patients only.

The only other trial published is the oldest kidney-specific telehealth-delivered dietary intervention conducted to date. In this non-randomised pre/post-test controlled trial, the effects of various dietary interventions for adherence to potassium and fluid requirements in haemodialysis patients were compared (Cummings et al., 1981). Four study groups received a behavioural contract (patient and nurse), a behavioural contract (patient and nurse and a family or friend), a control group, and a group who received weekly telephone follow-up for six weeks by a dialysis nurse, respectively. Attrition in the telephone group was 18% compared to 8%, 5% and 4% in the other groups. Baseline serum potassium and fluid was not reported across any study group, impacting the interpretation of the efficacy of the intervention. However, compared to the other behaviour change contract interventions, telephone contact resulted in the only significant reduction in serum potassium from baseline to follow up when compared to the control arm (F= 10.51, P < 0.05). Interestingly, 'general health beliefs' of haemodialysis patients did not predict their compliance, and the authors hypothesised that there must be other features of the telephone-based follow-up that influenced patients' dietary and fluid compliance. Serum potassium is insufficient to infer dietary compliance and thus this study is limited in its generalisability to dietary practice. However, the results are meaningful in its comparison of dietary interventions which may improve dietary adherence and is promising for informing telehealth interventions in kidney patient targeted programs.

With regard to telehealth-delivered dietary interventions that specifically measure changes in dietary behaviour, there is a paucity of telehealth interventions in people with CKD (GFR <60ml/min/1.73m^2). In addition to the three dietary telephone-based counselling interventions discussed above (in ESKD), the CKD literature has demonstrated improvements in CKD rated quality of life (Blakeman et al., 2014; Campbell, Ash, & Bauer, 2008; Li et al., 2014), and a pilot mobile phone text messaging intervention in ESKD was rated as 9.8 out of 10 for usefulness in medication and appointment reminders (Cueto-Manzano et al., 2015). These studies however, are based on small sample sizes (Blakeman et al., 2014; Cueto-Manzano et al., 2015), and did not contain a dietary intervention. Therefore, more robust interventions are required to both understand the feasibility, acceptability and overall effectiveness of telehealth-delivered dietary interventions in CKD.

2.7 Summary of the evidence

The long-term management of CKD requires people to adopt complex dietary recommendations. Such interventions are best facilitated via regular coaching to support sustained behaviour change. Dietary changes have historically targeted single nutrients rather than food-based dietary patterns, and such dietary pattern studies have not been well tested in CKD populations. Telehealth interventions can overcome patient-centred barriers to accessing face-to-face programs and provide feasible delivery methods, as they are ubiquitous and accessible regardless of geographic location. This may facilitate long-term contact with a healthcare professional. Utilising telehealth methods to deliver dietary interventions may be a viable option for the healthcare system in order to deal with the rising prevalence of chronic disease, and consequently increasing demand on healthcare resources. This opportunity is reflected in the increasing trajectory of trials over the last five years utilising telehealth methods for the delivery of lifestyle interventions. Although promising, the effectiveness of telehealth interventions is not conclusive. Whether telehealth could overcome the previously reported patient-centred barriers to adhering to diet recommendations remains unclear.

2.7.1 Identification of key gaps in the literature

1. *There is a need for systematically reviewed evidence of dietary patterns and associations with clinical outcomes in established CKD populations.*

While dietary patterns have low level evidence for associations with improved CKD outcomes, particularly albuminuria, mortality and CVD, this evidence **has not been systematically evaluated to date**. Furthermore, the **potential mechanisms** by which these dietary approaches might lead to these improved outcomes in established CKD populations **has not been thoroughly summarised in the scientific literature.**

This gap in the literature is addressed in thesis research question 1.

2. *There is a need for systematically reviewed evidence of the effectiveness of telehealth methods to achieve complex dietary change in chronic disease.*

The current body of literature generally supports the use of various telehealth methods in chronic disease. However, these reviews have translational limitations which need addressing. Specifically, they have not analysed dietary change as an independent outcome (thus not all diet results are summarised and/or reported in systematic reviews to date); they have focused on singular telehealth interventions (e.g. telephone only); commonly focus on only single disease states; or included short-term interventions, which are insufficient to assess sustainable dietary changes. At least two of these restrictions are present in all previous published telehealth reviews. **A gap in current knowledge is that the effect of telehealth-delivered dietary interventions for achieving complex dietary change in chronic disease is unknown.**

This gap in the literature is addressed in thesis research question 2.

3. *CKD patients' opinions are underrepresented and more patient-engagement is needed for informing possible dietary interventions in the future.*

People with kidney disease (dialysis and CKD) express preference for regular and repeated follow up to help them adhere to their dietary recommendations. However, **a gap in current knowledge is the delivery mode and method preferred by people with CKD in the context of the healthcare limitations** (Section 1.5). Furthermore, **the experiences and perspectives of people with CKD have about using technology as possible solutions to access on-going, repeated coaching have not been studied.**

This gap in the literature is addressed in thesis research question 3 and 4.

4. *The Australian Dietary Guidelines as a dietary pattern has not been trialled for its effectiveness on improving diet quality in people with stage 3-4 CKD.*

If a dietary telehealth intervention program is to be rolled out in CKD, **which has yet to be disseminated in scientific literature,** it is important to consider the complexity to dietary change, in which dietary requirements historically revolve around singular nutrients. Specific nutrient reducing strategies which ignore this complexity have long been plagued by poor compliance. Dietary patterns are not well tested in the CKD population, although the Australian Dietary Guidelines represent a healthy dietary pattern, which appears to be in-line with the many single nutrient recommendations/advice given to CKD patients, and now feature in the Australian evidence-based practice guidelines. This dietary approach has not been tested in CKD, and the effect of telehealth to deliver dietary education is unknown. Therefore, **a gap in current knowledge is the feasibility and acceptability of a telehealth-delivered intervention to facilitate adherence to the Australian Dietary Guidelines in stage 3-4 CKD**. Furthermore, the clinical **safety and effectiveness of a telehealth intervention aimed at improving overall diet quality (in-line with the Australian Dietary Guidelines) has yet to be determined in CKD to date**.

This gap in the literature is addressed in <u>thesis research questions 5 and 6</u>.

Chapter 3 - Beyond Sodium, Phosphate and Potassium: Potential Dietary Interventions in Kidney Disease

3.1 Preface

While the framework depicted in Table 1-1 details the steps in developing a telehealth program in CKD, the development of dietary approaches for telehealth interventions is not covered by this framework. This chapter provides a comprehensive overview of potential dietary interventions in people with kidney disease. Without first understanding what dietary approaches could work (in terms of adherence and clinical outcomes) in people with CKD, any subsequently developed telehealth program may fail or fall victim to the same patient-centred barriers that affect current dietary recommendations and interventions. This chapter explains the concept of dietary patterns, specifically a plant-based dietary pattern and how this type of dietary intervention may overcome many of the dietary adherence issues highlighted in Chapter 2. Finally, this chapter will address the potential mechanisms by which components of a plant-based dietary pattern works together to influence clinical outcomes, and highlights proposed approach to test these hypotheses in people with CKD.

This chapter contains the accepted version of an Editorial published in the peer-reviewed journal *Seminars in Dialysis*. The paper formatting has been modified in accordance with a consistent thesis style. However, the grammar, headings, and references (in-text and bibliography) are unaltered in accordance with the journal publishing guidelines.

Citation: **Kelly JT**, Rossi M, Johnson DW, Campbell KL. Beyond sodium, phosphate and potassium: Potential dietary interventions in kidney disease. *Seminars in Dialysis*. 2017; 30(3), 197-202.

3.1.1 Related work to this Chapter completed by the candidate

One other manuscript relating to this chapter has also been published by the candidate, in the form of another invited Editorial (Appendix E). While this Editorial is not a primary publication within this thesis, the candidate took the lead author role and uses this article to further articulate on the key concept presented in Chapter 2. Specifically, the paper reports on the concepts and mechanisms underpinning protein quality (animal and plant-based protein types) - this relates to thesis research question 1.

- **Kelly, JT,** Carrero-Roig, JJ. Protein Quality and CKD progression: protection may be in the pattern. *Journal of Renal Nutrition*. 2017; 27(4), 221-224.

3.2 Abstract

People with kidney disease are advised to restrict individual nutrients, such as sodium, potassium and phosphate, in line with current best practice guidelines. However, there is limited evidence to support the efficacy of single nutrient strategies, and compliance remains a challenge for clinicians to overcome. Many factors contribute to poor compliance with dietary prescriptions, including conflicting priorities for single nutrient restriction, the arduous self-monitoring required, and the health-related knock-on effects resulting from targeting these nutrients in isolation. This paper reviews the evidence-base for the overall pattern of eating as a potential tool to deliver a diet intervention in which all the nutrients and foods work cumulatively and synergistically to improve clinical outcomes. These interventions may assist in kidney disease management and overcome these innate challenges that single nutrient interventions possess. Healthy dietary patterns are typically plant-based and lower in sodium and animal proteins. These patterns may have numerous mechanistic benefits for cardiovascular health in kidney disease, most notably through the increase in fruit, vegetables, and plant-based protein, as well as improved gut health through the increase in dietary fiber. The evidence to date on optimal dietary patterns points towards use of a predominantly plant-based diet, and suggests its adoption may improve clinical outcomes in dialysis patients. However, clinical trials are needed to determine whether these diet interventions are feasible, safe and effective in this patient population.

3.3 Background

Diet has long been considered a modifiable risk factor for chronic kidney disease (CKD), and a key management strategy in end-stage kidney disease (ESKD). International guidelines for managing kidney disease have traditionally focused on the modification of the macro- and micro-nutrients such as protein, energy, sodium, potassium, phosphorous, and types of macronutrients, including fatty acids and sugars.[1, 2] This approach of individual nutrient modification can result in complex nutrition messages. Translating these into clear food-based recommendations is challenging. It comes as little surprise that food and fluid advice have been reported as ambiguous and frustrating by patients,[3] inherently restrictive[4] and have been shown to adversely impact overall diet quality.[5]

The aim of dietary management in patients with early stage CKD is to delay progression and reduce cardiovascular risk. Conversely, in dialysis patients, the focus is to mitigate protein-energy wasting and electrolyte disturbances (i.e. low potassium, low phosphorous, high calorie).[6] In contrast, a traditional cardio-protective diet targeting higher fiber, and lower saturated fat may be considered to be in direct conflict with low electrolyte and high calorie advice in CKD management.[7] Adopting an alternative whole-of-diet approach, which shifts focus onto foods, such as wholegrains, fruits, and vegetables, shows considerable promise with respect to pragmatically and effectively achieving the universal goals of retarding CKD progression and attenuating cardiovascular risk, whilst still avoiding serious electrolyte derangements.[4, 8]

This paper will consider historical evidence for individual nutrient-based restrictions, appraise and contrast new evidence and controversies, and discuss emerging, whole-of-diet strategies for the management of kidney disease and its complications.

3.3.1 Challenges with traditional individual nutrient approaches to nutrition management

Current international guidelines recommend patients receive individualised dietary interventions by a qualified dietitian focusing on individual nutrients, including salt, phosphate, potassium, protein and calories.[2, 9-12] These traditional single-nutrient focus recommendations present four key issues:

3.3.1.1 Poor evidence base underpinning individual nutrient strategies

Most studies examining individual nutrient modification strategies have been limited in methodologic quality. Studies in nutritional nephrology are plagued by small sample sizes, short follow-up and use of non-validated surrogate outcome measures,[2, 13-17] such that the effects of these approaches on patient-level outcomes, including ESKD and mortality, remain uncertain. For example, dietary salt reduction is considered a key dietary strategy in kidney disease, with strong evidence supporting a role for augmenting the pharmacological effects of antihypertensive medications and reducing blood pressure and albuminuria. However, the effects of long-term salt restriction on CKD progression and cardiovascular outcomes remain uncertain.[17-22] Similarly, dietary phosphate restriction has been advocated by many guidelines to ameliorate renal and cardiovascular risk. However, the evidence that change to dietary phosphorus intake can impact outcomes beyond serum measures is notably absent.[23, 24] Dietary potassium restriction for the prevention and management of hyperkalaemia is further advocated, particularly in more advanced forms of CKD. However, to date there have been no randomised-controlled trials evaluating the impact of potassium restriction on clinical events. In contrast, increased dietary potassium consumption is advocated in the general population in concert with dietary sodium restriction to reduce cardiovascular risk.[25] There is observational evidence of the benefits of this in CKD models on CV risk factors,[26] which provides further uncertainty.

Modified protein diets continue to be at the forefront of nutritional management for people with kidney disease. Low protein diets are favoured in CKD for ameliorating uraemia, kidney stone formation, gout, hyperphosphatemia, and gut-derived uremic toxins.[27] However, protein restriction trials report inconsistent findings and at best, provide a modest benefit for progression to ESKD[28] or mortality.[29] Meta-analysis shows protein reductions of 0.2g/kg/day delay CKD progression by only 0.5mL/min/year in both randomised and non-randomised trials.[30] In addition, compliance with low protein diets is poor,[5, 31] and can risk protein-energy wasting.[30, 32] It should therefore come as no surprise that there is a paucity of evidence supporting the assertion that low protein diets reduce the risk of progression to ESKD[28] or mortality.[29] As in CKD, most of the evidence in dialysis is based on observational studies, and in many instances the target protein intakes are rarely achieved.[33] This continues to challenge guidelines committees tasked with designing evidence-based protein recommendations.

3.3.1.2 Complex nutritional interventions impair dietary adherence

Individual nutrient modification can lead to complex nutritional messages, which people with kidney disease report to be confusing and constraining.[3-5, 34] Patients with CKD report dietary interventions to be burdensome[35] leading to overall poor adherence to dietary restrictions.[5, 36] A number of characteristics are known to influence a patient's ability to follow dietary recommendations, including a patient's knowledge, self-efficacy, motivation, and uremic-related factors.[37] Poor dietary adherence in CKD and dialysis populations may therefore place patients at risk of clinical complications, such as malnutrition, fluid overload and CVD. [5, 36, 38]

3.3.1.3 Conflict between competing priorities of individual nutrient strategies

When adopting an individual nutrient approach, translating these recommendations to food-based advice can create conflicting priorities. A key example is between dietary protein and phosphorous. In dialysis, a high protein intake with optimal phosphate management is associated with the best survival.[39] However, advice to increase protein intake to prevent protein-energy wasting may in fact introduce an increase in phosphorous intake due to the high phosphorous content in protein sources. As a result, this approach can compete with an increased risk of hyperphosphatemia.[39]

3.3.1.4 Health-related knock-on effects from restricting single nutrients

As mentioned above, the restriction of single nutrients is a challenging and complex task for people with kidney disease. In addition, the practical application of these individual nutrient restrictions can compromise the overall quality of the diet and be detrimental to one's health. For example, a dialysis patient may be instructed to restrict their potassium intake from fruits, vegetables and whole grains. The 'knock-on' consequences impact both nutrition and overall health. Avoiding these foods reduces the exposure to dietary fiber, limiting its therapeutic role in preventing constipation and as a pre-biotic in maintaining a healthy gut microbiome.[40]

Therefore, attempts to quantify and limit nutrient intake is a challenge for clinicians and problematic given the poor quality supporting evidence.[2, 9-11] It also presents an intense burden for people with kidney disease to implement day-to-day, and presents conflicting priorities which risk knock-on health consequences.

3.3.2 A move to dietary patterns: A potential paradigm shift in kidney disease

The change in dietary management of chronic diseases from a single nutrient focus, towards the overall patterns of eating may address some of these concerns. Dietary patterns consider the cumulative effect and synergy between the combinations of foods and nutrients, which are more applicable to chronic disease management.[41, 42] Healthy dietary patterns with evidence for mitigating CVD risk include the Dietary Approaches to Stop Hypertension (DASH) diet,[43] the Mediterranean diet,[44] vegetarian diets,[45, 46] and other patterns of eating consistent with dietary guidelines.[47, 48] Observational studies suggest these mentioned dietary patterns may be superior to single nutrient interventions,[49] particularly due to the cumulative effects of multiple nutrients consumed through diets rich in fruit and vegetables,[50] fish and omega-3 fatty acids,[51] legumes, wholegrain cereals and nuts,[52] and lower in sodium,[19] red meat,[53] saturated fats,[54] and common phosphate additives.[55]

There is a paucity of evidence for the effectiveness of changing dietary patterns in the established CKD population. However, emerging data support the belief that dietary patterns that follow the Healthy Eating Index, DASH, and the Mediterranean diet are associated with reduced renal-related mortality and slower progression to ESKD.[49, 56, 57] Preliminary data also suggest that adherence to the DASH diet may reduce the risk of ESKD incidence in people with established CKD,[58] and a small single arm trial demonstrated the DASH diet as safe in a CKD sample.[59] Other studies demonstrate that the DASH dietary pattern is associated with preserved residual kidney function and reduced overall incidence of CKD in community-dwelling individuals.[56, 60, 61]

Similarly, the Mediterranean diet has long-standing associations with reduced CVD incidence and mortality in the non-CKD population.[62-65] Within the CKD population specifically, it appears that the Mediterranean diet may be particularly effective in reducing systemic inflammation and microalbuminuria.[66] While no randomised controlled trials have been conducted in established CKD or dialysis populations to examine the effects of these diets on long-term patient-level outcomes, a recent meta-analysis of longitudinal studies demonstrated a healthy eating pattern was consistently associated with a 27% reduced risk of mortality in populations with established kidney disease.[8]

3.3.2.1 How can whole-of-diet approaches improve health outcomes?

The opportunity to educate people with kidney disease to achieve a healthy dietary pattern presents itself with many benefits in comparison to isolated nutrient interventions. The translation of nutrient-based recommendations is exceptionally challenging for patients to quantify without ongoing guidance and feedback on daily consumption of these nutrients.[34] In contrast, behavioural counselling to achieve a desired pattern of eating can lead to better compliance due to offering flexibility, choices to suit individual preferences, and a manageable change to a multitude of nutrients within the whole diet concurrently.[34]

Adopting a healthy dietary pattern has many mechanisms of benefit for cardiovascular health in CKD, most notably through the increase in fruit, vegetables and a predominance of plant-based protein.

3.3.2.2 Fruit and vegetables and cardiovascular health in kidney disease

Fruit and vegetables generate bicarbonate naturally as they release potassium-salts and decrease the renal acid load. In-fact, a diet higher in fruit and vegetable has been shown to more effectively manage metabolic acidosis compared to standard bicarbonate prescriptions.[67] In contrast, sulphur containing animal proteins are naturally acid-producing and can exacerbate acidosis.[58] Plant-based diets also limit the bioavailability of dietary phosphorus thereby decreasing absorption (due to the presence of phytate in vegetable forms of phosphorous),[68] particularly in comparison to higher animal protein diets.[45] Plant-based diets are also characteristically higher in fruit, vegetables and whole grains, which increase the exposure to dietary fiber, which in turn is linked to reduced inflammation and improved survival.[69]

3.3.2.3 Plant-based dietary patterns have different animal-plant protein ratios

Lowering the red meat-to-plant-based protein ratio has been described as likely ‘kidney sparing’ in CKD.[53, 70] Balanced portions from both red meat, fish and plant-based sources have been demonstrated in a cohort of 1355 haemodialysis patients to be associated with an appreciably lower risk of cardiovascular hospitalization death due to any cause compared with an unbalanced diet.[71] However, despite the theoretical benefits of a plant-based diet, studies regarding the safety and efficacy of increased fruit and vegetable intake over the long term are lacking in both CKD and dialysis populations. This evidence gap needs addressing before such diets can become routinely recommended in the kidney disease population.

3.3.2.4 Safety profile of a plant-based dietary pattern in the kidney disease population

Safety concerns regarding plant-based diets relate to the high fruit and vegetable intake. However, fruit and vegetable intake is typically low across the CKD spectrum and unnecessary restriction may risk many vitamin and mineral insufficiencies.[5] While fruit and vegetable intake conveys higher dietary potassium, it has been recently argued this does not necessarily translate into hyperkalaemia.[72] It was also recently demonstrated that adults with stage 4 CKD can safely increase their servings of fruit and vegetables to correct metabolic acidosis and reduce blood pressure without an appreciably increased incidence of hyperkalaemia.[73, 74] In addition, a higher fiber intake from a higher fruit and vegetable diet can prevent constipation in dialysis populations and facilitate faecal excretion of excess potassium, which can be up to 3.5 times greater than that of the general population.[74] This ability of intestinal potassium excretion to compensate for a reduction in renal potassium handling has called into question the priority for dietary restriction in hyperkalemic states.[72] Nonetheless, efficacy trials are needed to confirm the safety of plant-based diets.

3.3.2.5 Dietary patterns and manipulation of the gut microbiome

The bacterial community in the gut (termed the microbiota) contributes to digestion through fermentation and putrefaction,[75] and is able to be manipulated by plant-based dietary patterns which emphasize whole grain carbohydrates, higher intakes of fibrous fruits, vegetables, legumes and nuts.[75, 76] Gut dysbiosis is commonly observed in kidney disease populations and is a major contributor to the build-up of uraemic toxins. Indoxyl sulphate (IS) and p-cresyl sulphate (PCS) are two uremic toxins produced by the gut microbiome, which originate from protein metabolism in the gut and are associated with an increased risk of cardiovascular disease.[77]

It has been established that the concentration of these uremic toxins is increased by a high protein-to-fiber ratio in the diet.[78] Higher protein diets promote proteolytic (putrefaction) bacteria over saccharolytic (fermentation) bacteria, which in turn contributes to dysbiosis and a higher risk of cardiovascular disease.[79] Protein metabolism in the gut leads to the breakdown of tyrosine, phenylalanine, and tryptophan which are precursor products for PCS and IS conversion.[79] In contrast, the fermentation of fiber (non-digestible carbohydrate) releases short-chain fatty acids that favour healthy microbial activity to control dysbiosis.[80] Populations consuming a predominantly plant-based diet have greater microbiome abundance and biodiversity compared with populations consuming a diet subject to processing and inadequate fiber.[81] A high fiber vegetarian diet has also been shown to reduce the production of IS and PCS compared to a high meat diet in a healthy population,[46] which might translate to a reduced risk of CVD and mortality.

In the kidney disease population specifically, recent trials have demonstrated the roles of pre-biotics,[82] pro-biotics,[83] and their combination as synbiotics[84] to modulate the composition of the intestinal microbiota, thereby controlling the production of IS and PCS, and ultimately potentially mitigating CVD risk and mortality.[85] Improving the microbial diversity through synbiotics in kidney disease populations highlights an important role of the gut in mediating CVD risk, but also reaffirms the role of the overall quality of the diet. Specifically, a plant-based dietary pattern which contain natural pre-biotics[86] and is lower in red meat proteins represents an important strategy for reducing uremic toxin production naturally.[46] This dietary pattern is more likely to support the production of saccharolytic bacteria, generate short-chain fatty acids and improve cardiovascular risk and gastrointestinal health overall, beyond that of the single nutrient strategies targeting prebiotics, fiber, carbohydrates or protein in isolation.[78, 87]

3.3.3 Is a new paradigm shift in renal nutrition management on the horizon?

People with kidney disease are advised to restrict individual nutrients, in line with current best practice guidelines. However, patients face several challenges from conflicting priorities which often result in poor compliance. Recent evidence supports a shift in nutritional focus to a healthy dietary pattern which is predominantly plant-based to promote control over a range of clinical risk factors and end-points in kidney disease. This is likely an approach which could facilitate compliance with dietary change in kidney disease. In addition, the non-invasive manipulation of the gut microbiota through a plant-based diet which is high in natural prebiotics has promising clinical potential.

It is now timely to determine whether a predominantly plant-based diet is feasible, safe and effective in the management of CKD and dialysis. To test the important question of whether the adoption of healthy eating patterns could improve patient-level outcomes in the kidney disease population, high quality controlled clinical trials are needed. However, until a plant-based dietary pattern has been deemed both safe and effective, and tested using a pragmatic implementation strategy, these theories of what exactly constitutes a 'healthy' diet will continue to be hypothetical.

We do, however, know how frequently we currently fall short when focussing on individual nutrients, particularly sodium, potassium, phosphate and protein. Dietary management of dialysis patients may require a new approach emphasizing healthy eating patterns and a more broad based view of what constitutes success.

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Chapter 4 - Healthy Dietary Patterns and Risk of Mortality and ESRD in CKD: A Meta-Analysis of Cohort Studies

4.1 Preface

Chapter 3 highlights the possibility of a healthy dietary pattern and associations to improved clinical outcomes in CKD. Chapter 3 also addresses potential mechanisms by which a healthy dietary pattern may influence clinical outcomes and generates a hypothesis which may be a more pragmatic, understandable, and possibly more effective dietary approach than single nutrient restrictions.

With a lack of randomised controlled trial evidence of a dietary pattern and long-term CKD endpoints, cohort studies form the body of evidence with informs practice. However, cohort studies which have evaluated the association of health dietary patterns and CKD outcomes has not been systematically synthesised to date.

Chapter 4 reports on a systematic review which evaluated cohort studies for the associations of healthy dietary patterns with mortality and ESKD in established kidney disease populations. The purpose of this chapter is to address thesis research question 1 and determine whether dietary patterns may have a place in the dietary management of CKD.

This chapter contains the accepted version of an original manuscript published in the peer-reviewed journal, the *Clinical Journal of the American Society of Nephrology*. The paper formatting has been modified in accordance with a consistent thesis style. However, the grammar, headings, and references (in-text and bibliography) are unaltered in accordance with the journal publishing guidelines.

<u>Citation</u>: **Kelly JT**, Palmer SC, Wai SN, Ruospo M, Carrero JJ, Campbell KL, Strippoli GF. Healthy dietary patterns and risk of mortality and ESRD in CKD: A meta-analysis of cohort studies. *Clinical Journal of the American Society of Nephrology.* 2016; 12(2), 272-279.

4.1.1 Related work to this Chapter completed by the candidate

One other manuscript relating to this chapter has also been published by the candidate, in the form of an original research article (Appendix F). While this paper is not a primary publication within this thesis, the candidate supervised the student researcher who led this project and used the findings to augment the findings of Chapter 4 in an Australian setting. As this study is published outside the search date used in the review reported in Chapter 4, this work contributes important concepts and findings directly related to the research question this chapter addresses. Specifically, the associations of higher consumptions of fruit, vegetables and different dietary habits and hard clinical end-points in CKD stages 3-4.

- Wai SN, **Kelly JT**, Johnson DW, Campbell KL. Dietary patterns and clinical outcomes in chronic kidney disease: The CKD.QLD nutrition study. *Journal of Renal Nutrition.* 2016; 27(3), 175–182.

4.2 Abstract

4.2.1 Background and objectives

Patients with chronic kidney disease are advised to follow dietary recommendations that restrict individual nutrients. Emerging evidence indicates overall eating patterns may better predict clinical outcomes, however evidence for dietary patterns in kidney disease has not been previously synthesized.

4.2.2 Design, setting, participants and measurements

This systematic review aimed to evaluate the association between dietary patterns and mortality or end-stage kidney disease among adults with chronic kidney disease. Medline, Embase, and reference lists were systematically searched to 24 November 2015 by two independent review authors. Eligible studies were longitudinal cohort studies reporting the association of dietary patterns with mortality, cardiovascular events, or end-stage kidney disease.

4.2.3 Results

A total of seven studies involving 15,285 participants were included. Healthy dietary patterns were generally higher in fruit and vegetables, fish, legumes, cereals, whole grains, and fiber and lower in red meat, salt, and refined sugars. In six studies, healthy dietary patterns were consistently associated with lower mortality (3983 events; adjusted relative risk 0.73, 95% confidence interval 0.63 to 0.83; risk difference 46 fewer (29 to 63 fewer) events per 1000 people over five years). There was no statistically significant association between healthy dietary patterns and risk of end-stage kidney disease (1027 events; 1.04, 0.68 to 1.40).

4.2.4 Conclusions

Thus, healthy dietary patterns are associated with lower mortality in people with kidney disease. Interventions to support adherence to increased fruit and vegetable, fish, legume, whole grains, and fiber intake and reduced red meat, sodium, and refined sugars could be effective tools to lower mortality in people with kidney disease.

4.3 Introduction

Chronic kidney disease affects about 10% to 13% of adults[1] and represents a public health challenge due to the substantially increased risks of death and cardiovascular disease among affected people.[2 3] Patients who have chronic kidney disease are advised to follow dietary recommendations that restrict individual nutrients such as phosphorus, salt, potassium, and protein to prevent short- and long-term clinical complications.[4] Historically, dietary advice has been based on individual nutrients or food groups instead of whole eating patterns, although considered complex, challenging to adhere to, and an intense burden for some patients.[5] In addition, there is limited evidence that restricting or supplementing specific nutrients or single food groups effectively prevents clinical complications including kidney failure or death.[6-9] Fluid and dietary restrictions remain frequently identified as priority areas of research by patients with kidney disease and healthcare providers.[10]

Recent evidence has linked dietary patterns rich in fruit and vegetables, fish, legumes, cereals, and nuts with reduced cardiovascular events and death in healthy adults and those at high risk of cardiovascular disease.[11-14] In parallel, there is an emerging trend toward the study of whole dietary patterns rather than single nutrient or food group restrictions among people with kidney disease.[15-17] However, existing cohort studies of dietary patterns in people with kidney disease have small sample sizes, while existing randomized trials are insufficiently powered to establish the role of whole dietary patterns on mortality and kidney failure limiting the impact of single studies to inform clinical practice and policy.[18 19] Existing dietary guidelines lack robust evidence for effects on patient-centered outcomes.[20]

The aim of this study was to conduct a meta-analysis of the evidentiary basis for the association of dietary patterns with mortality and cardiovascular endpoints to establish the potential role of dietary patterns among people with chronic kidney disease.

4.4 Material and methods

Our primary aim was to assess the association of healthy dietary patterns on the risk of mortality and end-stage kidney disease in adults with chronic kidney disease. This systematic review followed a pre-specified review protocol, prospectively registered in the International Prospective Register of Systematic Reviews (PROSPERO)[21] and reported using the preferred reporting items for systematic reviews and meta-analysis (PRISMA).[22]

4.4.1 Data sources and Searches

We searched Medline, Embase, and reference lists of retrieved studies for prospective cohort studies available online reporting the association between dietary patterns and clinical outcomes among adults who have chronic kidney disease on November 30, 2015. We did not have any language or date restriction for the search. The search terms are shown in Appendix G.

4.4.2 Study Selection

Dietary patterns were defined as overall habitual food intake ascertained by healthy eating guidelines or *a priori* diet quality score; dietary pattern analysis; and/or consumption of whole food groups such as fruit and vegetables. We excluded single nutrient or food-group based modifications from this review including isolated protein or sodium restriction. We required follow up for at least 24 weeks to ensure sufficient follow-up of dietary patterns on patient-level outcomes, and explicit reporting of outcomes either as raw data or adjusted effect estimates with 95% confidence intervals. We used definitions of chronic kidney disease according to international clinical practice guidelines.[4]

4.4.3 Data Extraction and Quality Assessment

Two authors (JK, SW) independently reviewed all retrieved records for eligibility using reference management software. The two authors extracted data and adjudicated risk of bias, with differences resolved by discussion. We contacted authors for information missing or unclear from included studies. The risk of bias was assessed using the Newcastle-Ottawa tool.[23] We then used the grading of recommendations assessment, development, and evaluation (GRADE) methodology to rate the quality of the evidence for mortality as high, moderate, low or very low.[24] Observational studies begin as low quality evidence, but can be rated upward to moderate or high quality evidence if they collectively demonstrate a large magnitude of effect, or a dose-response gradient. Outcomes were death, health-related quality of life, end-stage kidney disease, major cardiovascular events, blood pressure, serum cholesterol, and major adverse events.

4.4.4 Data Synthesis and Analysis

We carried out analyses according to a pre-defined protocol to compare healthy eating patterns (generally higher intake of fruit, vegetables, cereals, legumes, whole grains and fiber, and fish, and lower intake of red meat, salt, and refined sugar) versus dietary intake less representative of these eating patterns. We then summarized adjusted risks (hazard ratio, odds ratio or relative risk) provided in studies using random-effects inverse variance meta-analysis. A fixed-effect model was also used to ensure robustness of the model chosen and susceptibility to outliers. Estimated numbers of events incurred or avoided with dietary change was calculated as a risk difference based on a five year risk of mortality reported in a systematic review of cohort studies.[25] We used the I^2 statistic to assess heterogeneity – the proportion of total variation observed in the association of dietary intake and outcome among studies beyond that expected by chance, with an I^2 value less than 25% considered as low heterogeneity and more than 75% as high heterogeneity. We assessed for small study effects in analyses for mortality by visual evaluation of the funnel plot for symmetry.

Sensitivity analyses were done excluding studies in which the same cohort of participants may have been represented more than once and excluding studies involving adults with end-stage kidney disease. We planned subgroup analyses based on gender, duration of follow up, study quality, and geographical region. Analyses were performed using Stata 13, with 95% confidence intervals excluding a risk ratio of 1.0 used to denote statistical significance.

4.5 Results

4.5.1 Study Selection and Baseline Characteristics

The systematic search yielded seven cohort studies (Figure 4-1) involving 15 285 patients with chronic kidney disease (Table 4-1).[17 26-31] The participants were followed for between 4 and 13 years on average, totalling approximately 91 000 patient years of follow up. All but one study involved people with chronic kidney disease defined as an estimated glomerular filtration rate below 60-70 ml/min per 1.73 m^2 body surface area or albuminuria.[17 26-30] One study enrolled adults treated with dialysis.[31] Studies involved people living in the United States,[17 26 27 29 30] Sweden,[28] and Japan.[31] Healthy dietary patterns were reported as generally consistent with a higher intake of fruits and vegetables, legumes, cereals, whole grains and fiber, and fish, and lower intake of red meat, and products containing sodium and refined sugars (Table 4-2). All studies were published between 2013 and 2015. There were 3983 deaths and 1027 end-stage kidney disease events recorded during follow up.

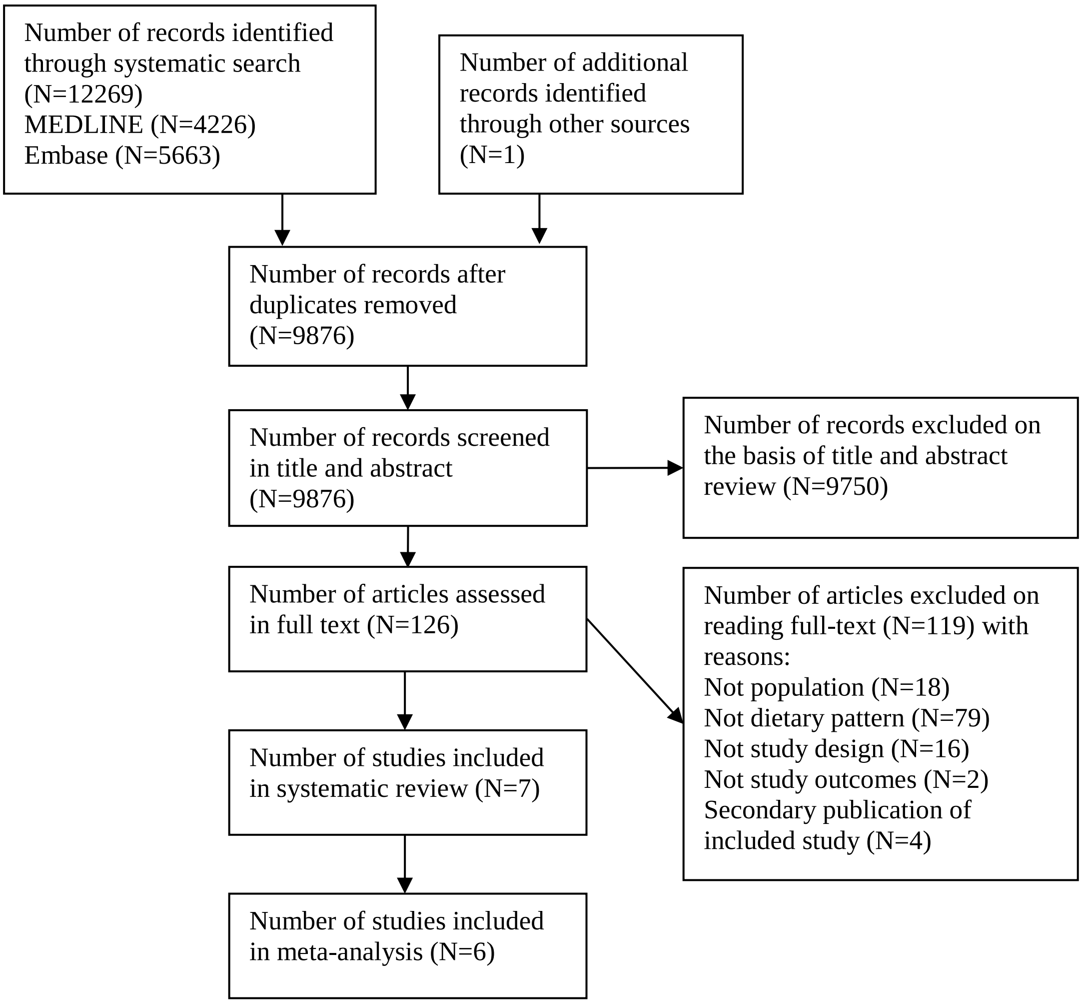

Figure 4-1: Flow chart describing process of study selection.

4.5.2 Risk of Bias and Evidence Quality

Risks of bias in the included studies is shown in Figure 4-2. Overall, studies were considered at low risk of bias for characteristics considered important to the reliability of cohort studies. When GRADE (directness, precision, consistency, and study limitations) recommendations were considered, the evidence quality for all-cause mortality was considered low based on the non-randomized study design, without incurring further downgrades in evidence quality for indirectness, imprecise results, heterogeneity, or study reporting limitation.

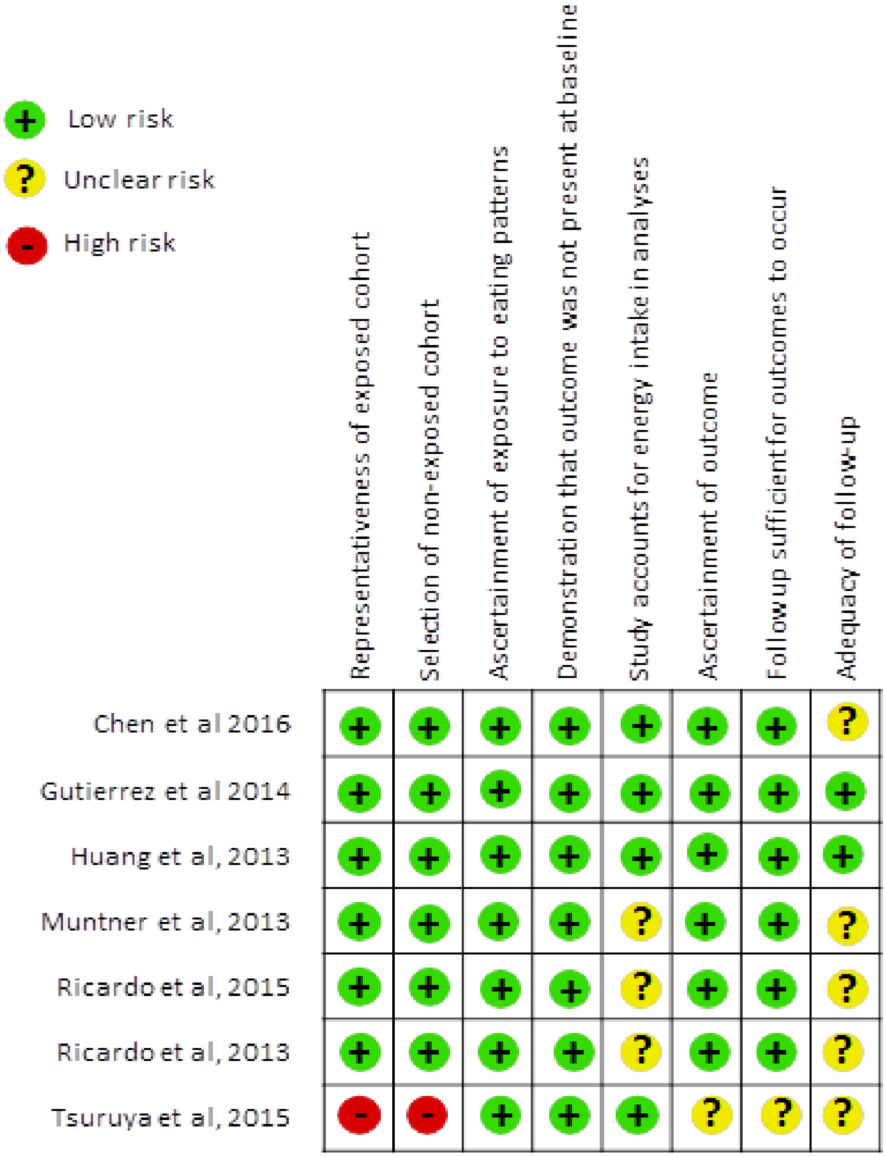

Figure 4-2: Quality assessment of included studies using Newcastle-Ottawa scale.

Table 4-1: Characteristics of included studies.

First author	Dietary pattern	Country	Study name	No. of participants	Years of follow-up (person-years) *	Definition of kidney disease	Age at entry (mean or median)	Estimated glomerular filtration rate, mean ± SD (ml/min/1.73 m^2)	Endpoints (no. of events)
Chen et al, 2016[26]	Plant versus animal protein	United States	Third National Health and Nutrition Examination Survey (NHANES III)	1065 men and women	6.2 years (6603)	Estimated glomerular filtration rate <60ml/min/1.73m^2	20 years or older (not reported)	101 ± 20 (quartile 1)	All-cause mortality (633)
Gutiérrez et al, 2014[27]	Plant based	United States	Reasons for Geographic and Racial Differences in Stroke (REGARDS) study	3972 men and women	6.4 years (25,421)	Estimated glomerular filtration rate <60ml/min/1.73m^2 or urine albumin: creatinine ratio >30mg/g	45 years or older (67.1-69.8 years)	68.1 (standard error 0.8) (quartile 1)	All-cause mortality (816); end-stage kidney disease (141)

First author	Dietary pattern	Country	Study name	No. of participants	Years of follow-up (person-years) *	Definition of kidney disease	Age at entry (mean or median)	Estimated glomerular filtration rate, mean ± SD (ml/min/1.73 m^2)	Endpoints (no. of events)
Huang et al, 2013[28]	Mediterranean diet	Sweden	Uppsala Longitudinal Study of Adult Men	506 men	9.9 years (4648)	Estimated glomerular filtration rate <60ml/min/1.73m^2	Approximately 70 years	51.9 (median) (interquartile range 46.3-56.6)	All- cause mortality (168)
Muntner et al, 2013[29]	Diet score (fish; fruit/vegetables, sodium, sugar fiber, carbohydrate)	United States	Reasons for Geographic and Racial Differences in Stroke (REGARDS) study	3093 men and women	4 years (12,372)	Estimated glomerular filtration rate <60ml/min/1.73m^2	45 years or older (72.2 years)		All-cause mortality (610); end-stage kidney disease (160)

First author	Dietary pattern	Country	Study name	No. of participants	Years of follow-up (person-years) *	Definition of kidney disease	Age at entry (mean or median)	Estimated glomerular filtration rate, mean ± SD (ml/min/1.73 m^2)	Endpoints (no. of events)
Ricardo et al, 2015[17]	American Heart Association	United States	Chronic Renal Insufficiency Cohort (CRIC) Study	3006 men and women	4 years (12,024)	Estimated glomerular filtration rate 20-70ml/min/1.73m^2.	21 to 74 years (58 years)	43.39 ± 13.34 (diet score 0)	All-cause mortality (437); chronic kidney disease progression (50% decrease in eGFR or end-stage kidney disease) (726); atherosclerotic events (355)
Ricardo et al, 2013[30]	Healthy Eating Index based on Food Guide Pyramid	United States	Third National Health and Nutrition Examination Survey (NHANES III)	2288 men and women	13 years (29,744)	Estimated glomerular filtration rate <60ml/min/1.73m^2 or urine albumin: creatinine ratio >30mg/g	20 years or older (59 years)	88.4 ± 1.7 (standard error of mean) (healthy lifestyle score quartile 1)	All-cause mortality (1319);

First author	Dietary pattern	Country	Study name	No. of participants	Years of follow-up (person-years) *	Definition of kidney disease	Age at entry (mean or median)	Estimated glomerular filtration rate, mean ± SD (ml/min/1.73 m^2)	Endpoints (no. of events)
Tsuruya et al, 2015[31]	Meat, fish and vegetable intake	Japan	Japan Dialysis Outcomes and Practice Patterns Study (JDOPPS)	1355 men and women	Not reported	Hemodialysis	Not reported (61.4 years)	Dialysis	All-cause mortality or hospitalization due to cardiovascular disease (not reported)

4.5.3 Outcomes

4.5.3.1 All-cause mortality

When compared with other dietary patterns, a dietary pattern richer in vegetables, fruit, fish, cereals, whole grains and fiber, legumes, and nuts and seeds and lower in red meat, sodium and refined sugars was associated with a lower risk of death. In six studies among 13 930 participants followed for between 4 and 13 years the relative risk of all-cause mortality was 0.73 (95% confidence interval 0.63 to 0.83) (Figure 4-3). There was no heterogeneity between studies (I^2 =0%) and no evidence of small study effects (Figure 4-5). Based on an estimated five year mortality of 17% in people with chronic kidney disease,[25] the risk difference with a healthy dietary pattern compared to other dietary patterns was 46 fewer deaths per 1000 people (29 to 63 fewer) over 5 years.

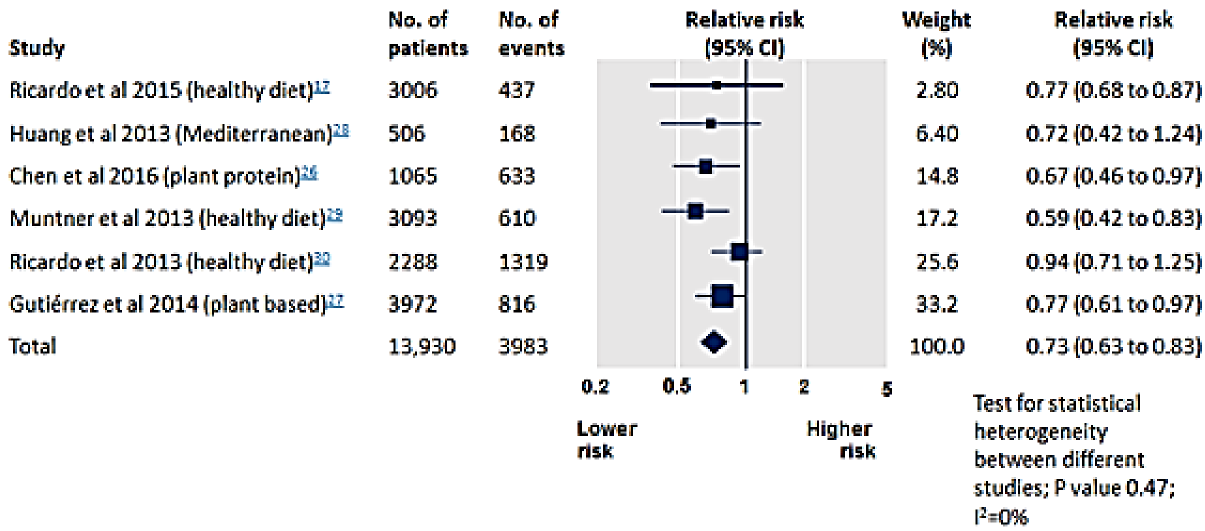

Figure 4-3: Risk of all-cause mortality associated with healthy dietary patterns among adults with chronic kidney disease.

4.5.3.2 End-stage kidney disease

There was no evidence of an association between a healthy dietary pattern and risk of end-stage kidney disease in three studies (n=10 071 people) with follow up ranging between 4 and 6.4 years. The risk of end-stage kidney disease among people with chronic kidney disease was 1.04 (0.68 to 1.40) with no evidence of statistical heterogeneity between studies (Figure 4-4).

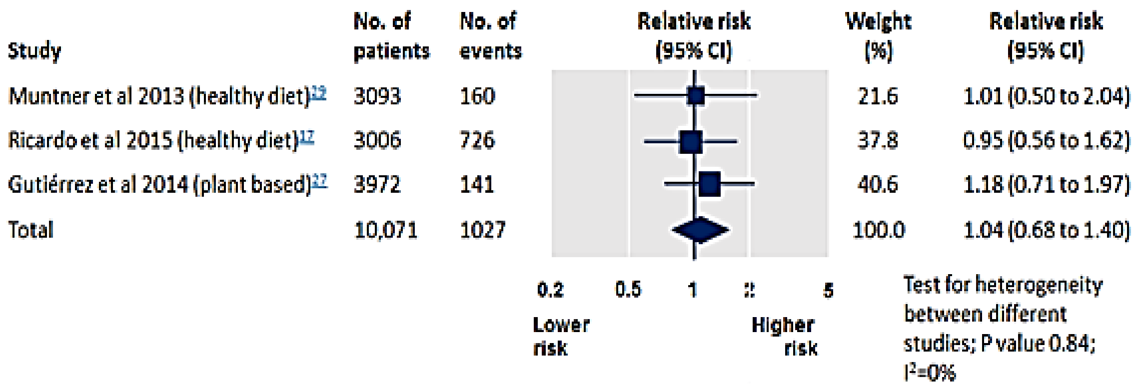

Figure 4-4: Risk of end-stage kidney disease associated with healthy dietary patterns among adults with chronic kidney disease.

4.5.3.3 Major cardiovascular events, health-related quality of life, adverse events, blood pressure

There were insufficient numbers of studies to conduct meta-analysis for risks of major cardiovascular events. In one study involving 3006 people, a healthy diet score was not associated with risk of atherosclerotic events (1.01, 0.47 to 2.18).[17] In a single study among 1355 dialysis patients, an “unbalanced dietary pattern” with high sodium intake and higher vegetable and lower fish and meat intake, was associated with a higher risk of a composite of hospitalization due to cardiovascular disease or death due to any cause.[31]

There was no reporting of health-related quality of life, or cardiovascular-related death, adverse events, or hyperkaliemia as individual endpoints. There was no information about the effects of healthy dietary patterns on blood pressure or serum cholesterol levels during follow up.

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Table 4-2: Characteristics of dietary exposures used in meta-analyses

Study	Dietary pattern	Dietary exposure	Exposure category	Reference category	Covariates included in risk ratio
Chen et al, 2016[26]	Plant versus animal protein	Plant protein ratio quartiles (grains, fruits, vegetables, legumes, nuts, and seeds)	Quartile 4 >43.5% plant protein ratio	Quartile 1 <25.3% plant protein ratio	Total protein intake, age, sex, race, smoking, alcohol use, calorie intake, exercise, body mass index, hypertension, cancer, myocardial infarction, congestive heart failure, stroke and diabetes
Gutiérrez et al, 2014[27]	Plant based	Plant based defined using principal component analysis (fruits, vegetables, fish)	Quartile 4 (highest)	Quartile 1 (lowest)	Age, gender, race, geographic region, energy intake, lifestyle factors (self-reported frequency of exercise; current smoking), comorbidities (heart disease; hypertension), educational achievement, family income, urinary albumin to creatinine ratio, estimated glomerular filtration rate
Huang et al, 2013[28]	Mediterranean diet	Mediterranean diet score (polyunsaturated fats/saturated fatty acids >0.34; vegetables and legumes >69 day; fruit >115 g/day; cereals and potatoes >361 g/day;	High adherence (dietary score 6-8)	Low adherence (dietary score 1-2)	Body mass index, physical activity, smoking status, education, hypertension, hyperlipidemia, and diabetes

Study	Dietary pattern	Dietary exposure	Exposure category	Reference category	Covariates included in risk ratio
		fish >25 g/day; meat and meat products <92 g/day; milk and milk products <328 g/day; alcohol moderate			
Muntner et al, 2013[29]	Diet score	Healthy diet score based on fish (≥ servings/week), fruit and vegetable consumption (≥4.5 cups/day) and sodium (<1500 mg/day), sugar (<450 kcal/week), fiber/carbohydrate ratio intake (>0.1)	Intermediate dietary score (2-3 components)	Poor dietary score (0-1 components)	Age, race, sex, geographic region, income, education, history of stroke and coronary heart disease.
Ricardo et al, 2015[17]	American Heart Association	Healthy diet score (American Heart Association; fruits/vegetables>2.8 cups/day; fish >1.3 oz/week; whole grains >0.88 oz/day; 24-hour urine sodium excretion <152 mEq/day; sweets/sugar-sweetened beverages <571 ml/week	Ideal (healthy diet score 4-5	Dietary score 0-3	Clinical center; age, sex, race/ethnicity, education, diabetes, dyslipidemia, hypertension, any cardiovascular disease, angiotensin-converting enzyme/angiotensin receptor blocker use; estimated glomerular filtration rate, urine protein excretion.

Study	Dietary pattern	Dietary exposure	Exposure category	Reference category	Covariates included in risk ratio
Ricardo et al, 2013[30]	Healthy Eating Index based on Food Guide Pyramid	Healthy Eating Index based on 10 dietary components (grains, vegetables, fruits, milk, meat, total fat, saturated fat, cholesterol, sodium, and dietary variety)	Healthy Eating Index score 73.1-100	Healthy Eating Score <54.5	Age, sex, race/ethnicity, annual household income, education, estimated GFR, microalbuminuria, diabetes, cardiovascular disease, cancer, systolic blood pressure, serum cholesterol, use of statin, use of angiotensin-converting enzyme inhibitor.
Tsuruya et al, 2015[31]	Meat, fish and vegetable intake	Consumption of approximately equal amounts of food from meat, fish, and vegetable groups.	Well-balanced	Unbalanced	Age, gender, dialysis duration, serum albumin, body mass index, energy intake, diabetes, coronary heart disease, cerebrovascular disease and peripheral vascular disease.

Abbreviations: GFR = glomerular filtration rate.

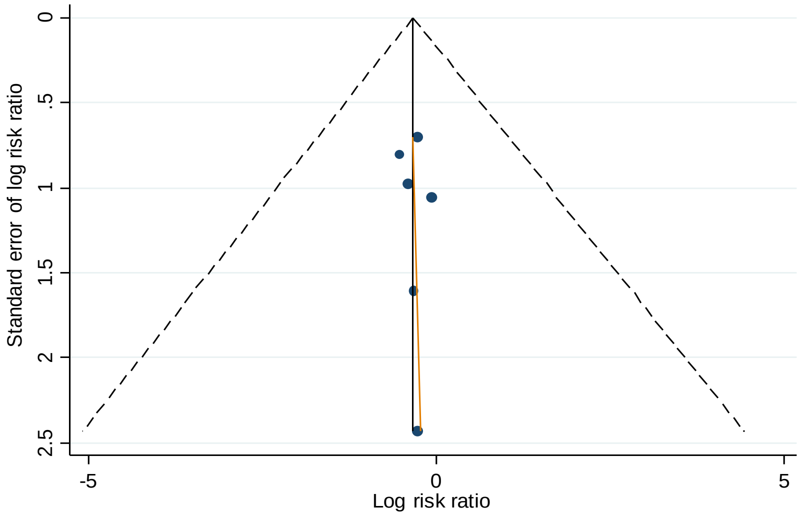

Figure 4-5: Funnel plot for the meta-analysis of the risks of all-cause mortality for healthy eating patterns compared to other eating patterns

4.5.4 Sensitivity analyses

Results were similar when single studies were removed to exclude the possibility that participants had been included in analyses more than once (Table 4-3). There was no evidence that results in meta-analyses for mortality were different based on country of origin, age, duration of follow up time, or quality of studies (Table 4-4).

Table 4-3: Risk ratio for all-cause mortality in sequential meta-analyses with one study removed

Study removed	Cohort	Risk ratio of all-cause mortality with study removed	p-value for association	Risk ratio of ESKD with study removed	p-value for association
Chen et al, 2016[26]	NHANES III	0.77 (0.66 to 0.90)	0.001	--	--
Gutiérrez et al, 2014[27]	REGARDS	0.74 (0.61 to 0.90)	0.002	0.97 (0.64 to 1.48)	0.89
Huang et al, 2013[28]	Upsala	0.75 (0.64 to 0.88)	0.001	--	--
Muntner et al, 2013[29]	REGARDS	0.79 (0.68 to 0.92)	0.003	1.06 (0.74 to 1.54)	0.75
Ricardo et al, 2015[29]	CRIC	0.75 (0.64 to 0.88)	<0.001	1.12 (0.74 to 1.69)	0.60
Ricardo et al, 2013[30]	NHANES	0.70 (0.60 to 0.83)	<0.001	--	--

NHANES III - Third National Health and Nutrition Examination Survey; REGARDS - Reasons for Geographic and Racial Differences in Stroke study; Uppsala - Uppsala Longitudinal Study of Adult Men; CRIC - Chronic Renal Insufficiency Cohort (CRIC) Study. The remaining study by Tsuruya et al was not included in the meta-analysis.

Table 4-4: Subgroup analysis for all-cause mortality

Variable (No of studies)	Relative risk (95% CI)
Duration:	
<6.3 years (3)	0.63 (0.48 to 0.78)
>6.3 years (3)	0.81 (0.67 to 0.95)
Country of origin:	
USA (5)	0.73 (0.61 to 0.85)
Other (1)	0.73 (0.63 to 0.83)
Age:	
> 60 years (3)	0.69 (0.57 to 0.82)
< 60 years (2)	0.73 (0.63 to 0.83)
Study quality:	
Lower (4)	0.72 (0.55 to 0.89)
Higher (2)	0.73 (0.63 to 0.83)

4.6 Discussion

This meta-analysis comprising approximately 90 000 person years of follow up and including 3983 mortality events showed that dietary patterns rich in vegetables and fruits, legumes, whole grains, and fiber together with lower consumption of red meat, sodium, and refined sugars were consistently associated with lower mortality in people with chronic kidney disease. Existing cohort studies provide evidence of the association of healthy dietary patterns with risks of end-stage kidney disease, and major cardiovascular complications, or health-related quality of life, although there is considerable uncertainty in the results for these outcomes due to wide confidence intervals from meta-analyses that included few studies. To our knowledge this is the first cumulative assessment of whole dietary patterns and their association with mortality and clinical complications in people with chronic kidney disease.

The association of healthy dietary patterns with lower mortality in people with chronic kidney disease is in contrast with the lack of association between restrictions of individual dietary components for food groups including serum phosphorus,[7 32 33] sodium[6] and protein[34] intake and mortality, although individual studies addressing these questions have had small sample sizes and low power to discern the relative association of nutritional modifications on clinical outcomes. The findings of the current meta-analysis are consistent with accruing large-scale evidence of consistent mortality benefits with adherence to a plant-based dietary pattern among people without existing chronic disease[35] although in a large randomized controlled trial of Mediterranean diet, a primarily plant-based diet including extra virgin olive oil or nuts, there was no statistical evidence of lower mortality alone in people at high risk of cardiovascular events, while a Mediterranean dietary pattern lowered the risk of a composite of non-fatal and fatal cardiovascular events.[11] To date, randomized trials testing the effects of dietary patterns rich in fruits and vegetables or a Mediterranean diet in adults with kidney disease are preliminary and have not examined mortality as an endpoint.[18 36 37] As in our study, there is limited evidence for the association of eating patterns with risks of end-stage kidney disease in the literature, although cohort studies suggest dietary patterns rich in fruit and vegetables may lower risks of progression to chronic kidney disease and decrease albuminuria and blood pressure.[38-42]

Recent research in chronic kidney disease has seen a shift from the decades-long focus on assessing and modifying single nutrient components of diet among people with chronic kidney disease reflecting in practice guidelines,[4] to an increasing analysis of whole dietary patterns. As a result, this study shows accumulating evidence over the last five years of analyses that consider all food groups thought to be important for health. While existing single-nutrient approaches have had limited impact on health in people with kidney disease, this study of the building evidence for healthy dietary patterns on mortality risk suggests that this shift to wider dietary approaches across several food groups is appropriate and aligns with existing patient priorities.[10] Given the prevalence of chronic kidney disease in the community, data supporting specific dietary patterns potentially has an important public health impact, and warrants the prioritization of additional resources to support a randomized trial of dietary intake in this population. Highly-efficient trial design, embedded within registries or electronic health records might increase the feasibility and reduce the costs of an adequately powered dietary trial in the wider population with kidney disease. This is particularly relevant given the progressive shift toward more Western dietary patterns[43] and the relative lack of treatments proven to lower the burden of premature death and kidney failure among people with kidney disease. A recent additional cohort study showing a dose-dependent association between red meat intake and risk of end-stage kidney disease and lower risks when other sources of protein are substituted further adds weight to the need to understand the association of whole food dietary patterns with clinical outcomes in the setting of kidney disease.[44]

While this study was prospectively planned and conducted independently by two authors, providing highly consistent findings among studies, and precise risk estimates for the mortality endpoint, some limitations of this study can be identified. First, the healthy dietary patterns we identified were not standardized, and represent a heterogeneous range of dietary intake. For example, some dietary patterns included milk products as healthy food groups[27] whereas others defined milk and milk product intake as less desirable.[26 28 30] However, the key elements of greater fruit and vegetable intake were present in all studies. Second, these studies were based on dietary self-recalls via differing methods (food frequency questionnaires versus food records), although the results among all studies were consistent, and not apparently influenced by this factor. Third, included patients had a range of kidney function, although all had an estimated glomerular filtration rate below 60-70 ml/min per 1.73 m^2 or albuminuria. Fourth, all the studies included in meta-analysis for mortality were conducted in United States or Sweden, and thus the results may not be generalizable to other global regions including lower resourced regions. Fifth, we did not find any association of dietary change with end-stage kidney disease. End-stage kidney disease is a rarer complication of chronic kidney disease due to the competing risk of death; accumulated studies evaluating the associations of diet with this outcome had relatively few recorded events as would be expected, even when linked to dialysis census databases. Sixth, it was not possible to assess for evidence of publication bias. Finally, this study is based on non-randomized data leading to the potential for the findings to be partly explained by residual confounding and leading to lower quality evidence. The results are hypothesis-generating and represent an important indication for a future randomized trial and public policy, particularly as dietary and lifestyle interventions are highly ranked research priorities by patients and clinicians.

In summary, this meta-analysis shows that adherence to dietary patterns rich in fruit and vegetables, fish, legumes, cereals, whole grains and fiber, and lower in red meat, and products containing sodium and refined sugars is associated with lower mortality in people with chronic kidney disease. This finding represents a shift in evidence from management of single nutrient or food groups in the care of kidney disease and aligns with the experiences of patients who describe nutritional advice as frequently complex and difficult to follow. This evidence might prompt the prioritization of randomized trials of dietary patterns among people with kidney disease and re-evaluation of dietary advice as a public health tool to lower mortality in people with kidney disease.

4.7 Disclosures

GFMS has received an honorarium from Servier, GFMS has done consultancy for Danone;

KC and JJC are members of the Kidney Disease: Improving Disease Outcomes (KDIGO) Clinical Practice Guidelines for Nutrition in chronic kidney disease, co-sponsored by the US Academy of Nutrition and Dietetics and the US National Kidney Foundation.

KC is on the Kidney Health Australia Caring for Australasians with Renal Impairment guideline committee for guidelines on Autosomal Polycystic Kidney Disease including role as section chair for "Diet and Lifestyle Management". KC reports personal fees from Shire Australia.

JJC reports being council member of the International Society of Renal Nutrition and Metabolism (ISRNM), and general secretary of the European Renal Nutrition (ERN) working group of the European Renal Association-European Dialysis and Transplantation Association (ERA-EDTA). JJC also reports receiving honoraria during 2015 for lecturing at scientific symposia organized by Abbott Nutrition and Baxter Healthcare on topics related to this study.

JK, SP, SNW, MR have no relationships with companies or non-financial relationships that might be relevant to the submitted work.

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Chapter 5 - Telehealth methods to deliver dietary interventions in adults with chronic disease: a systematic review and meta-analysis

5.1 Preface

As outlined in Chapters 3 and 4, adherence to single nutrient dietary interventions is notoriously poor in people with CKD. With suggestions in the literature that this may relate to a lack of regular support and contact with health care professionals, it is important to evaluate the effectiveness of telehealth delivery methods for the delivery of complex dietary interventions and whether this could impact dietary change outcomes.

As shown in Table 2-8 and discussed in Chapter 2, there have been a number of telehealth systematic reviews conducted in chronic diseases. However, no review to date has investigated complex dietary change, in which a multitude of nutrients and/or foods are typically advised to be modified in the diet simultaneously. This is the type of dietary education reflective of true dietary management in clinical care and chronic disease management and requires regular and on-going support to facilitate sustained behaviour change.

Chapter 5 seeks to systematically address thesis research question 2, to determine what telehealth programs have been conducted in chronic disease populations, what content has been utilised, and what is their overall effectiveness on facilitating dietary change. The study reported in this chapter may assist in the understanding of what dietary interventions can be delivered using telehealth and what telehealth modalities may be more appropriate in complex chronic disease (such as CKD).

This chapter contains the accepted version of an original manuscript published in the peer-reviewed journal *The American Journal of Clinical Nutrition*. The paper formatting has been modified in accordance with a consistent thesis style. However, the grammar, headings, and references (in-text and bibliography) are unaltered in accordance with the journal publishing guidelines.

Citation: **Kelly JT**, Reidlinger DP, Hoffmann TC, Campbell KL. Telehealth methods to deliver dietary interventions in adults with chronic disease: a systematic review and meta-analysis. *The American Journal of Clinical Nutrition.* 2016; 104(6), 1693–1702.

5.1.1 Related work to this Chapter completed by the candidate

Two other manuscripts relating to this chapter have also been published by the candidate, in the form of a) a systematic review protocol (available in Appendix A) describing the methods for the paper presented below; and b) a (descriptive) original research article which is not a primary publication within this thesis, but was originally conceived by the candidate and supervisory team as a research study to build on the understanding of telehealth intervention reporting. This second paper reports on the study which evolved into a student project, for which the candidate took a supervisory role and assisted in completing the template for intervention description and replication (TIDieR) checklist for all studies included in Chapter 5, and those excluded due to not reporting dietary outcomes. The descriptive study findings are directly related to the research question this chapter addresses and is available in Appendix H.

- **Kelly JT**, Reidlinger DP, Hoffmann TC, Campbell KL. Telehealth methods to deliver multifactorial dietary interventions in adults with chronic disease: A systematic review protocol. *Systematic Reviews.* 2015; 4(1), 1-7.
- Warner M, **Kelly JT**, Reidlinger DP, Hoffmann TC, Campbell KL. Reporting of telehealth-delivered dietary intervention trials in chronic disease. *Journal of Medical and Internet Research.* 2018; 19(12).

5.2 Abstract

5.2.1 Background

The long term management of chronic disease requires adoption of complex dietary recommendations, which can be facilitated by regular coaching to support sustained behavior change. Telehealth interventions can overcome patient-centred barriers to accessing face-to-face programs and provide feasible delivery methods, accessible regardless of geographic location.

5.2.2 Objective

We performed a systematic review to assess the effectiveness of telehealth dietary interventions for facilitating dietary change in adults with chronic disease.

5.2.3 Design

A structured search was conducted in Medline, EMBASE, CINAHL, and PsychINFO (from inception until November 2015). Randomized controlled trials which evaluated multifactorial dietary interventions in adults with chronic disease which provided diet education in an intervention longer than four weeks in duration were considered. Meta-analyses were performed using random-effects model on diet quality, dietary adherence, fruit and vegetables, sodium intake, energy and sources of dietary fat.

5.2.4 Results

A total of 25 studies were included, involving 7,384 participants. Telehealth dietary intervention was effective at improving diet quality (Standardised Mean Difference (SMD) 0.22 [95% confidence interval: 0.09, 0.34]; p=0.0007), fruit and vegetable intake (Mean difference (MD) 1.04 servings/day [0.46, 1.62];p=0.0004), and dietary sodium intake (SMD -0.39 [-0.58, -0.20]; p=0.0001). Single nutrients (total fat and energy consumption) were not significantly modified by telehealth intervention, however important clinical outcomes were significantly improved by following a telehealth intervention, such as systolic blood pressure (mean difference (MD) -2.97mmHg [95% CI: -5.72, -0.22];p=0.05), total cholesterol (MD -0.08 mmol/L [95% CI: -0.16, -0.00]; p=0.04), triglycerides (MD -0.10 mmol/L[95% CI: -0.19, -0.01];p=0.04), weight (MD -0.80kg [95% CI: -1.61, 0]; p=0.05), and waist circumference (2.08 [95% CI: -3.97, -0.20]; p=0.03).

5.2.5 Conclusion

Telehealth-delivered dietary interventions which targeted whole foods and/or dietary patterns can improve diet quality, fruit and vegetable intake, and dietary sodium intake and where applicable should be incorporated into health care services for people with chronic conditions.

5.2.6 Keywords

Telehealth, diet quality, dietary, diet, fruit, vegetables, chronic disease

5.3 Background

Chronic diseases are the leading cause of ill health, accounting for over 68% of all deaths worldwide (1). Chronic diseases are characterised by a multi-factorial aetiology (1), which is often diet-related, including obesity, heart disease, diabetes, hypertension, stroke, and kidney disease (2). Self-management and the adoption of a healthy lifestyle, such as improved dietary habits, increased physical activity, and other health related behaviors (e.g. smoking cessation) are considered essential for the management of chronic diseases (3, 4). However, standard chronic disease care models are only followed by a minority of patients for many reasons including poor compliance and high patient burden (5). This suggests the long term maintenance of dietary behaviors is unable to be facilitated using traditional models of care.

Individuals with multiple risk factors for cardiovascular disease (CVD) and other chronic diseases have been identified as having higher levels of non-attendance in face-to-face (FTF) consultations (6, 7). Patient-centred barriers including limited transport and geographical isolation, working hours, and forgetting about appointments can contribute to appointment non-attendance (8). Additional healthcare barriers which can further hinder access to traditional FTF care include administrative error, access to clinic facilities, parking and unfavourable opening hours of clinics (7).

Telehealth technologies can be used to provide education and self-management support to facilitate and sustain lifestyle changes and have several advantages over traditional FTF models of care (9). Telehealth strategies may assist with achieving dietary behavior change in chronic disease (9-11) and are flexible in time and location, with the potential to offer intensive interventions that may not be feasible with traditional care models. According to the World Health Organisation (12), the term 'telehealth' refers to the delivery of health care services from a distance synchronously (i.e. same time, different location) and/or asynchronously (i.e. different time, different location), using information and communication technologies to exchange health information (12). A telehealth lifestyle intervention may offer flexibility in delivery mode involving the provision of health education or counselling individuals or group remotely via the telephone (13), computer or the internet (14-16) video (17), email (18), and/or mobile applications including text and photo messaging (19, 20).

Whilst there have been a number of systematic reviews covering different combinations of telehealth in healthy (21-23) and chronic disease (24-27) populations, none have specifically evaluated interventions that attempt to change dietary patterns or target multiple dietary changes simultaneously (such as multiple food groups or nutrients). These diet interventions represent the dietary advice typically provided to chronic disease populations (28). This systematic review therefore aimed to assess the overall effectiveness of telehealth dietary interventions for facilitating multifactorial dietary change in adults with chronic disease.

5.4 Methods

This systematic review followed a pre-specified review protocol, previously published elsewhere (29), detailing the rationale, purpose and methodology. It was prospectively registered in PROSPERO: The International Prospective Register of Systematic Reviews (CRD42015026398).

5.4.1 Literature search

A literature search was performed in the electronic databases, MEDLINE, EMBASE, CINAHL, and PsychINFO (since inception until November 2015), using a variety of subject headings, free text terms and synonyms relevant to the review in consultation with an experienced systematic review search librarian, and published in the protocol (29). There was no date or language restriction in the search strategy. A multi-step search approach was taken to retrieve relevant studies using forward and backward citation searching, expert correspondence, searching conference abstracts, theses and dissertations (ProQuest), and the International Clinical Trials Register (ICTRP) Search Portal and ClinicalTrials.gov to identify ongoing trials. This review follows the format recommended in the Preferred Reporting Items for Systematic Reviews and Meta-Analysis: The PRISMA Statement (30). The screening of articles was independently by two review authors, with disagreements in judgement resolved by consensus or a third reviewer.

5.4.2 Study selection

All search results were merged into EndNote™ and de-duplicated before screening. Studies were included in the review if they met all of the following criteria: 1) randomized controlled trial (RCT), cluster RCT, or quasi-RCT; 2) adult participants (>18 years of age); 3) conducted in a population with an established diet-related chronic disease defined as obesity (BMI $\geq 30 kg/m^2$), diabetes mellitus, heart disease, hypertension, stroke, or kidney disease (29, 31); 4) involved the provision of multifactorial dietary education where the dose of total intervention contact hours and/or the total number of interaction contacts was at least 50% delivered by at least one telehealth strategy; 5) developed or delivered by a qualified health professional (such as a nurse, dietitian, or physician); 6) reported on any measure of dietary intake at baseline and at least four weeks later at follow-up.

We defined a multifactorial dietary intervention as targeting more than a singular nutrient and/or food group. Multifactorial dietary interventions included: those aimed at overall dietary quality (assessed as any outcome which objectively scores adherence to dietary guidelines) (32-34) and patterns, such as the Mediterranean diet (35), and/or the Dietary Approaches to Stop Hypertension (DASH) diet (36), or those which educate about two or more dietary components (nutrients and/or food groups) simultaneously. Studies that targeted two or more diet changes within the same nutrient (e.g. manipulation of categories of fatty acids) were excluded as the dietary components related to one nutrient only, and thus were not classified as multifactorial.

Studies were included if they compared a telehealth intervention to usual care (as defined by trial authors); to dietary education in a FTF or group-based environment with no telehealth component; or via methods where less than 50% of the intervention was delivered by telehealth; or to a non-dietary focussed intervention.

The primary outcome was dietary intake (any measure), with secondary outcomes relating to clinical outcomes such as all-cause mortality; cardiovascular mortality; hospitalizations; and clinical markers of chronic disease progression, such as blood pressure, weight, and blood lipid profiles.

5.4.3 Data extraction and management

The following data were extracted from included studies: intervention details (following the components outlined in the Template for Intervention Description and Replication (TIDieR) checklist) (37), participant characteristic (chronic disease, age and gender), attrition, sample size, and study design and duration. Risk of bias was assessed by two review authors independently using Cochrane methodology (38) to categorise selection bias, performance bias, detection bias, attrition bias, and reporting bias in each study as low, unclear or high risk of bias. Mean, standard deviation, standard error or 95% confident intervals (CI) for all pre-specified primary and secondary outcome data that were reported at baseline and follow-up were extracted for analysis. When a study presented adjusted and unadjusted values, the most adjusted value was extracted for analysis.

5.4.4 Statistical analysis

To calculate the overall treatment effect on primary and secondary outcomes, the difference between the intervention and comparison groups' change scores from baseline to the end of follow-up was extracted. If change from baseline values was not available, end of intervention values were extracted, assuming baseline values were similar. The variance was calculated from the standard deviation or standard error from the difference between baseline and follow-up, or from confidence intervals when these values were not available (38). When interventions and associated outcomes were assessed as sufficiently homogeneous and when sufficient information was available from the studies, quantitative data were pooled into Revman (Version 5.3, The Cochrane Collaboration 2014) for meta-analysis using the DerSimonian and Laird random-effects model (39) and checked using the fixed-effect model to ensure robustness and susceptibility to potential outliers. The I^2 statistic was used to assess the inconsistencies between studies and describe the percentage of variability in effect. Heterogeneity was considered substantial if the I^2 statistic was ≥50%.

Effect sizes (for combined fruit/vegetables servings, energy intake, blood pressure, weight, and lipid profiles) were converted to standard units and calculated as mean differences (MD). Effect sizes for diet quality scores, dietary adherence, sources of dietary fat and sources of dietary sodium intake were calculated as standardised mean differences (SMD) due to the variability in outcome measures. We imputed missing standard deviations for one study in the dietary sodium and systolic blood pressure (SBP) analysis (40) using data from a similar included study utilizing similar methods and sample sizes (41, 42), as recommended (43). Egger's plot was explored to assess potential publication bias. Sensitivity analyses were conducted to explore statistical heterogeneity for results of studies that appeared heterogeneous to the results of other analysed studies including large studies and high risk of bias studies. Subgroup analyses were also conducted on different chronic health conditions (e.g. diabetes, CVD); studies using different telehealth strategies; studies targeting specified single food groups or nutrients (e.g. modifying sodium, fat, fruit and/or vegetables interventions) versus dietary patterns, and multiple lifestyle education interventions versus solely dietary education.

5.5 Results

5.5.1 Characteristics of included studies

The flow of study identification and selection is detailed in the PRISMA flow chart (Figure 5-1). The search identified 6967 studies. After duplicates were removed and non-relevant studies (n=5608) were excluded, a remaining 370 were subject to full text review. After this, 345 studies were excluded, leaving 25 for inclusion, involving 7,384 participants. Table 5-1 details the characteristics of the included studies including the frequency of contact, delivery provider, and type of dietary education. In all but four studies (42, 44-46), dietary education was delivered as part of a multifactorial lifestyle intervention. Studies were conducted in CVD (15 studies) (40-42, 46-57), diabetes (five studies) (44, 58-61), end-stage kidney disease (ESKD) (two studies) (45, 62), obesity (one study) (14), and in a mix of CVD and diabetes (two studies) (13, 63). The duration of studies ranged from eight weeks (46, 48, 56) to eight years (61). Telehealth delivery varied from the telephone (13 studies) (13, 40-42, 48, 50, 54, 56, 57, 59, 61-63), short message service (SMS; four studies) (45, 49, 51, 58), the internet (three studies) (14, 53, 55), video (one study) (47) or videoconferencing (one study) (60), and using a mix of telehealth methods (three studies) (44, 46, 50). The percent of the interventions delivered by telehealth methods varied across the included studies from 66-100 percent.

All included studies reported measures of dietary intake at baseline and follow-up. Studies varied in dietary outcome measures used and included: diet quality (three studies), dietary adherence (seven studies), energy intake (three studies), measures of dietary fat (eight studies), dietary sodium (seven studies), and intake of fruit and/or vegetables (nine studies). Ten studies were unable to be statistically pooled into meta-analysis and are therefore presented narratively (Table 5-2).

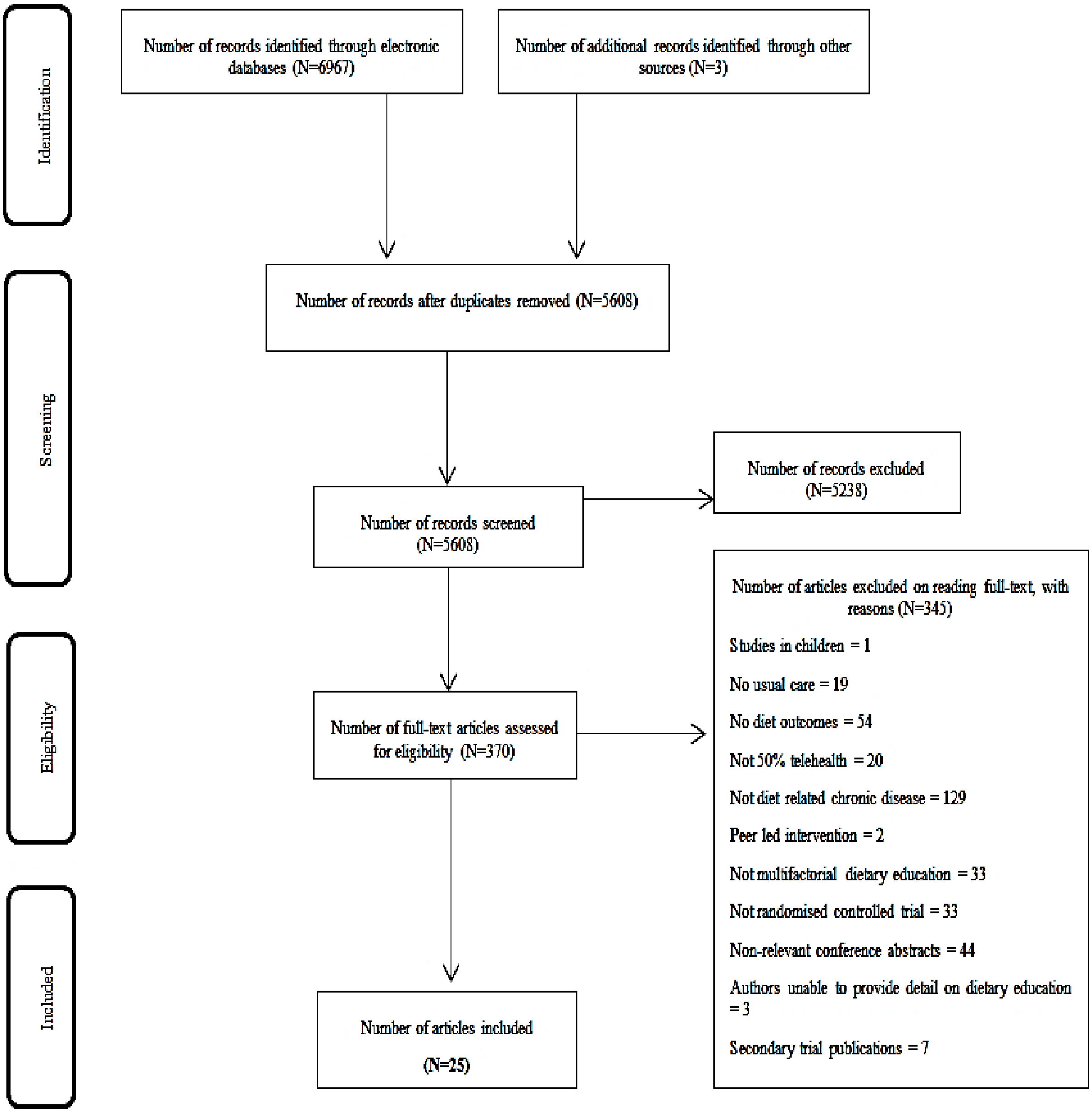

Figure 5-1: PRISMA flow chart describing process of study selection

5.5.2 The effect of telehealth interventions on dietary change

5.5.2.1 Diet quality

A total of three studies involving a total of 992 participants measured diet quality (40, 41, 59) using a diet quality score (40), the Australian Healthy Eating Index (59), and the DASH diet score (41). Telehealth intervention improved diet quality (SMD 0.22 [95% CI: 0.09, 0.34];p=0.0007; I^2= 0%) compared to non-telehealth comparators (Figure 5-2). The results remained significant in two trials with 12 (40) and 24 (59) month follow-up (SMD 0.18 [95% CI: 0.02, 0.33; p=0.02; I^2= 0%].

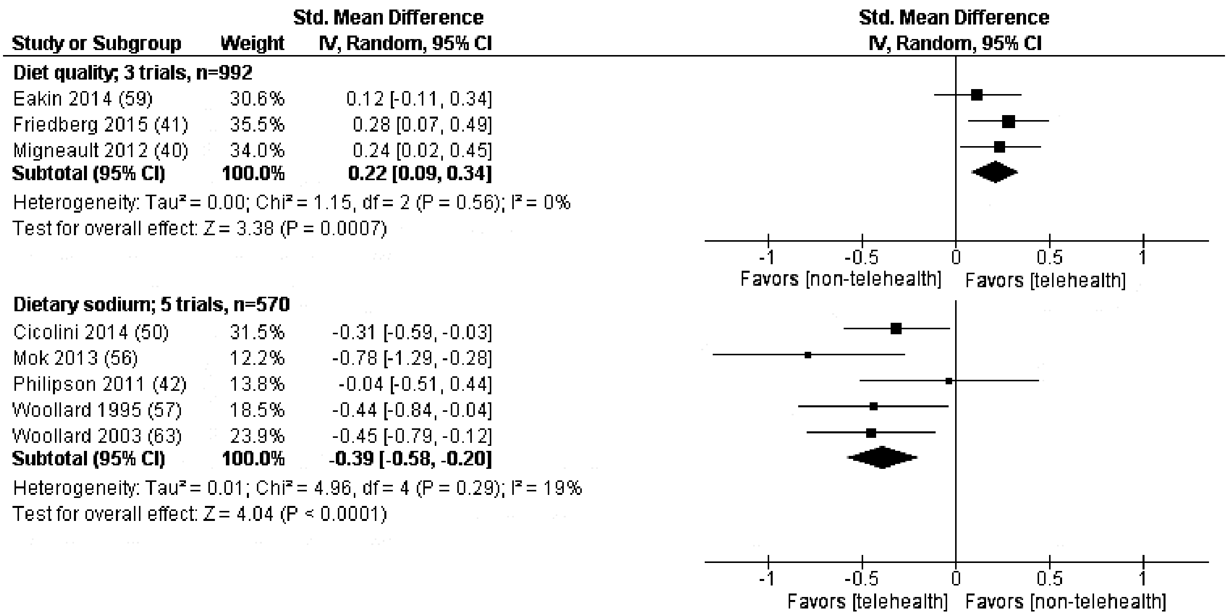

Figure 5-2: Forest plot of the effect of telehealth dietary intervention on diet quality and dietary sodium. The effectiveness of telehealth is presented using random effects. The mean and SD of changes from baseline are reported for trials. Effects of trial are presented as weight (%) and standardised mean difference (95% CI).

5.5.2.2 Diet adherence

Dietary adherence outcomes (seven studies) (45, 48, 52, 56, 58, 60, 62) were unable to be pooled into meta-analysis due to the variation in outcome reporting statistics which could not be standardised, and are presented narratively in Table 5-2. Overall, telehealth intervention significantly improved diet adherence compared to non-telehealth comparators as reported by trial authors in 57% (n=4) of the studies.

5.5.2.3 Fruit and vegetable intake

A total of nine studies reported on fruit and vegetable intake (13, 14, 44, 46, 49-51, 53, 54). Telehealth intervention significantly increased fruit and vegetable intake by 1.04 servings per day ([95% CI: 0.46, 1.62]; p=0.009; I^2= 70%) in four studies with five comparisons (2147 participants), and by 2.94 servings ([0.91, 4.97];p=0.005; I^2= 84%) per week in two studies with four comparisons (1682 participants) (Figure 5-3). Three studies were unable to be pooled statistically and are reported in Table 5-2. The one trial with longer term 12 month (13) follow-up supported this finding (MD 0.65 [95% CI: 0.02, 1.28; p=0.04].

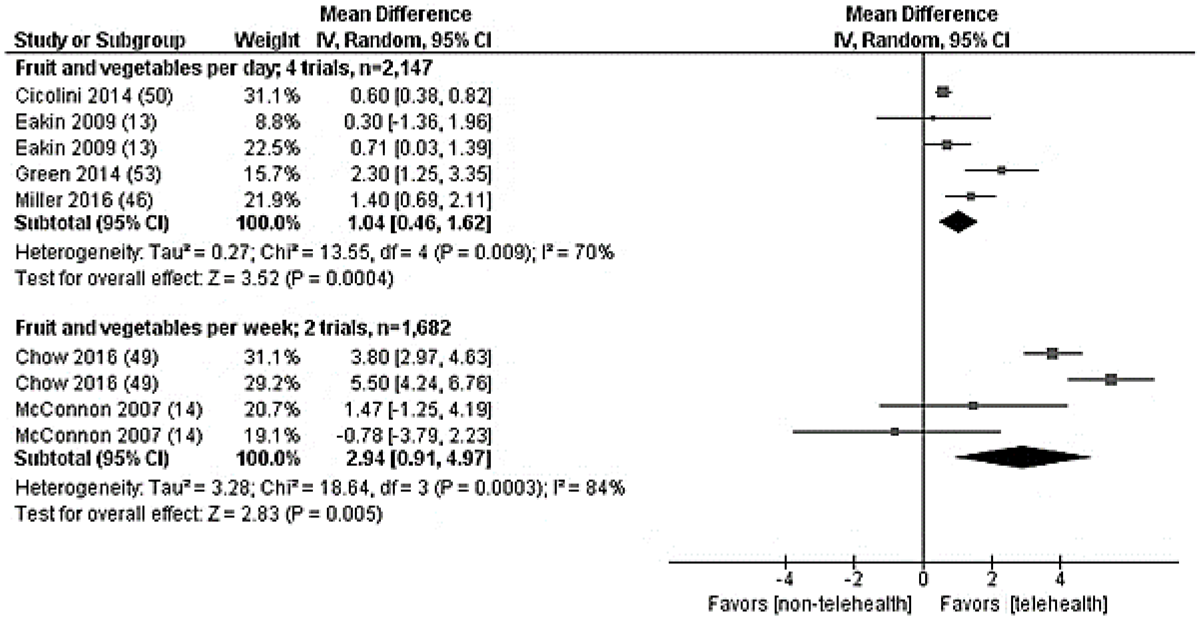

Figure 5-3: Forest plot of the effect of telehealth dietary intervention on servings of fruit and vegetable intake. The mean and SD of changes from baseline are reported for trials. Effect of trial are presented as weight (%) and mean difference (95% CI).

In the per day analysis, four of the five comparisons used the telephone and one used the internet (14), a sensitivity analysis showed intervention using the telephone resulted in an increased fruit and vegetable intake by 0.77 servings per day ([95% CI: 0.39, 1.14]; p=0.0001), with heterogeneity reduced (I^2= 35%) in the four comparisons (2057 participants). Dose of intervention showed weekly contact led to a higher intake (MD 1.32 servings/day [95% CI: 0.38, 2.26];p=0.006; I^2=85%) in three studies (46, 50, 53), than monthly contact (MD 0.27 servings/day [95% CI: 0.02, 0.52];p=0.03;I^2=0%) (13, 44). The one trial with longer term 12 month (14) follow-up was not significant.

Table 5-1: Characteristics of included studies according to the TIDieR checklist

Author, Year	Methods	Delivery method and provider	Telehealth intervention content	Comparator	Outcomes
Albert, 2007 (47)	RCT 3 months HF: n= 112	Video and telephone Nurse and Doctor	*Materials and procedure:* Video Guide on self-care behaviours and self-management actions. 60 min duration; 6 chapters: (a) basic CHF definition and symptoms; (b) treatment plan; (c) core HF medications; (d) nutrition (2000 mg sodium diet and fluid restriction); (e) active exercise and (f) lifestyle (regular activity and visits with healthcare provider). *Location:* Participant's home (community/ambulatory setting) *Dose and timing:* Participants free to watch at own leisure (variable among sample)	Standard HF care (Once-off education from physician and handbook)	1. Forget to restrict sodium intake (%) 2. HF hospitalisations (n)
Arora, 2013 (58)	RCT 6 months DM: n=128	SMS Designed by MDT consisting of endocrinologist, qualitative researcher and diabetes educator input	*Materials and procedure:* SMS messages designed to enhance motivation, self-efficacy, and ability to perform self-care behaviour. SMS Scheduling: (a) 1/day Education and motivational (based on the national DM education program) for BGL, BP, TC, healthy eating (increase fruit/vegetable & wholegrains, less saturated fat), PA, recipes and social support. (b) Medication reminders (3/week). (c) Healthy living challenges (2/week). (d) Trivia (2/week) to engage participants. Compensation for participants $175 during the 6 months *Location:* community/ambulatory setting. *Dose and timing:* Two daily unidirectional SMS messages in English or Spanish delivered to participants.	Usual care, detailed not defined	1. SDSCA general diet score 2. SDSCA specific diet score 3. SDSCA exercise score 4. HbA1C (%)

Author, Year	**Methods**	**Delivery method and provider**	**Telehealth intervention content**	**Comparator**	**Outcomes**
Chiu, 2010 (48)	RCT 8 weeks HTN: n=63	FTF and telephone Nurse	*Materials and procedure:* Telephone calls assessed participant's knowledge and behaviour in BP control, use of medication, BP home monitoring, exercise, diet, smoking, alcohol consumption, body weight control and stress management; reinforcing health self-management behaviours, providing health advice, and assessing the need for referrals; reviewing and revising the health goals. Dietary adherence education (sodium restriction, control of fat intake, and adequate fruit/vegetable consumption). Treatment for co-morbidities and/or stress were referred to other members in the healthcare team if needed. Location: In nurse clinic and community/ambulatory setting *Dose and timing:* Fortnightly contact	Received routine BP nurse clinic consultation	1. Diet adherence (sodium, fat restriction and consumption of fruit & vegetable score) 2. Exercise adherence (score) 3. SBP (mmHg) 4. DBP (mmHg)
Chow, 2016 (49)	RCT 6 months CHD: n=652	SMS Developed by clinicians, study personnel, academics and patient population	*Materials and procedure:* Text messages were regularly sent (semi-personalized) providing advice, motivation, and education based on the Australian Heart Foundation Healthy Living Guidelines. Message content was developed for 4 modules: smoking, diet, physical activity, and general cardiovascular health (non-smokers did not receive stop smoking SMS messages). The general module of messages included information generally provided by secondary prevention programs, such as chest pain action plans, guidelines, medications and adherence.	Usual care included community follow-up as determined by their physicians. Both groups received 3 study SMS messages providing their	1. Fruit (servings/week) 2. Vegetables (servings/week) 3. SBP (mmHg) 4. DBP (mmHg) 5. TC (mg/dL) 6. LDL (mg/dL) 7. HDL (mg/dL) 8. TG (mg/dL) 9. BMI (kg/m^2) 10. WC (cm) 11. PA (minutes/week)

Author, Year	Methods	Delivery method and provider	Telehealth intervention content	Comparator	Outcomes
			Location: community/ambulatory setting. *Dose and timing:* SMS messages delivered to participants 4 times a week.	allocation assignment, study contact details, and a reminder prior to the follow-up appointment	
Cicolini, 2014 (50)	RCT 6 months HTN: n=198	Telephone and Email Nurse	*Materials and procedure:* The recommendations were based on guidelines on healthy lifestyle and included: a diet rich of vegetables, lower sodium, saturated fat intake and TC, moderate PA (no guideline listed), smoking cessation, moderate alcohol consumption (no guideline listed), blood pressure self-monitoring and medication adherence. *Location:* community/ambulatory setting. *Dose and timing:* Weekly contact with participants.	Usual care, routine follow-up visits 1, 3 and 6 months after enrollment.	1. Fruit intake (servings/day) 2. Salt consumption (teaspoon/day) 3. PA (minutes/day) 4. SBP (mmHg) 5. DBP (mmHg) 6. TC (mg/dL) 7. LDL (mg/dL) 8. TG (mg/dL)
Dale, 2015 (51)	RCT 6 months CHD: n=116	SMS Nurse	*Materials and procedure:* Semi-tailored, bidirectional messaging was used - participants were prompted to SMS in their weekly pedometer step counts and to ask questions. Recommended lifestyle changes included stopping smoking, limiting alcohol consumption (< 14 drinks/week), eating 5 servings of fruit/vegetables per day while decreasing sodium and saturated fat content, and encouraging regular PA (150 minutes of moderate-to-vigorous intensity/week). Reponses to step counts were automated and based on the number of	Usual care, inpatient rehab (one 1-hour outpatient education program per week for 6 weeks) covering CVD risk factors, lifestyle	1. Vegetable/fruit intake >5 servings/day (%) 2. PA (% physically active) 3. BMI (kg/m^2) 4. SBP (mmHg) 5. DBP (mmHg) 6. TC (mmol/L) 7. LDL (mmol/L) 8. HDL(mmol/L)

Author, Year	Methods	Delivery method and provider	Telehealth intervention content	Comparator	Outcomes
			steps achieved, whereas individual questions were responded to personally by the research team. Participants were reimbursed for any costs associated with SMS messaging. *Location:* community/ambulatory setting. *Dose and timing:* Participants received 7 messages/week (1/ day) and had access to a supporting website.	change, and psychosocial support. Participants were offered a 16 session supervised exercise program.	
Eakin, 2009 (13)	RCT 12 months HTN or T2DM: n=434	Telephone Dietitian	*Materials and procedure:* Participants were mailed a workbook containing information on PA and nutrition, along with a pedometer. Telephone coaching followed motivational interviewing techniques and the constructs of social–cognitive theory. Personalized plan provided for modifying PA and diet; arranging telephone follow-up support. Intervention followed Australian National Guidelines for PA (150 minutes/week over five or more sessions of moderate-level PA), nutrition (2 fruit 5 vegetables, >30% E from fat, >10% E from saturated fat). *Location:* community/ambulatory setting. *Dose and timing:* Dietary coaching provided in every telephone call once/month.	Control group received a one page feedback on their assessment, and standard brochure for PA and nutrition.	1. Fat intake (% EEI) 2. Saturated fat intake (% EEI) 3. Vegetable intake (servings/day) 4. Fruit intake (servings/day) 5. Fibre intake (grams/day) 6. PA (minutes/week)
Eakin, 2014 (59)	RCT 24 months T2DM:	Telephone Dietitian	*Materials and procedure:* Participants sent a pedometer and a set of digital scales. Telephone coaching aimed to increase PA, reduce energy intake, and behavioural therapy. Benefits of weight	Control group received brief summary of each	1. Diet quality (0–100) 2. Energy intake (MJ) 3. PA (min/week) 4. HbA1C %

Author, Year	Methods	Delivery method and provider	Telehealth intervention content	Comparator	Outcomes
	n=249		loss (5–10%), setting short term goals for PA (30 min/day moderate-intensity, resistance 2-3 sessions/week), dietary intake, tracking progress, and problem solving discussed each call. Each participant received individualized advice to encourage a decrease energy intake by 2,000 kJ by following a low-fat diet (i.e. total fat <30% energy; saturated fat <7% energy) with sufficient dietary fibre (25 g/day for women; 30 g/day for men). *Location:* community/ambulatory setting. *Dose and timing:* Dietary coaching provided in every telephone call which was weekly for 1 month, fortnightly for 5 months then once a month.	assessment including standard diabetes practices.	5. Weight loss (kg) 6. WC (cm) 7. TC (mmol/L) 8. LDL (mmol/L) 9. HDL(mmol/L) 10. TG (mmol/L) 11. SBP (mmHg) 12. DBP (mmHg)
Ferrante, 2010 (52)	RCT 16 months HF: n=1518	Telephone Nurse	*Materials and procedure:* Telephone calls utilized to reinforce the content of an education booklet (describing HF, importance of drug and diet compliance, self-control and non-scheduled medical appointments are important). The intervention had 5 objectives: diet compliance, drug therapy, monitoring symptoms, PA, and fluid control. Nurses could adjust diuretic dose and suggest unscheduled visits to the cardiologist, and them as needed during the performance of the program. *Location:* community/ambulatory setting. *Dose and timing:* Calls were fortnightly then determined by the nurse, which was governed by a set protocol to determine need/risk.	Treated by cardiologist according to usual care practice	1. Issues with following healthy diet (%) 2. HF admissions (n) 3. ACM (n) 4. CVD admission (n) 5. All-cause admission (n)
Friedberg,	RCT	Telephone	*Materials and procedure:* The telephone coaching	Usual care,	1. DASH score

Author, Year	Methods	Delivery method and provider	Telehealth intervention content	Comparator	Outcomes
2015 (41)	6 months HTN: n=353	Psychologist or social worker	targeted diet, exercise, and medication, tailored and targeted to behaviours based on their current stage of change. Specific recommendations, such as trimming visible fat from meat and asking for sauces on the side in restaurants were provided each month, and any additional dietary questions were answered if patients were having trouble. Advice to increase fruit/vegetables and reduce dietary sodium was also given. PA adherence was defined as self-reported aerobic exercise for ≥3 days/week for ≥20 minutes each time. *Location:* community/ambulatory setting. *Dose and timing:* Dietary coaching was provided at every call once a month.	detail not defined	2. SBP (mmHg)
Glasgow, 2000 (44)	RCT 6 months T2DM: n=160	Tablet and telephone Researcher – profession NP	*Materials and procedure:* The computer interaction assessed, immediately analysed and provided feedback on the participant's dietary patterns, barriers and support for dietary self-management, and preferences for different intervention strategies. A tailored dietary fat reduction goal based on the participant's eating patterns and preferences was provided with a 1-page goals printout. Telephone follow up provided ongoing support and reinforcement to participants. The phone calls also provided personalized problem-solving based on barriers to dietary self-care identified via the touch-screen assessment. *Location:* In outpatient office (computer	Basic intervention received a general pamphlet about low-fat eating. All subjects attended baseline assessment - interactive multimedia touch-screen computer	1. Fruit & vegetables (Kristal scale) 2. Fat (Kristal scale) 3. HbA1C (%) 4. TC (mg/dL) 5. Weight (lb)

Author, Year	Methods	Delivery method and provider	Telehealth intervention content	Comparator	Outcomes
			interaction), and community/ambulatory setting for telephone follow-up. *Dose and timing:* once off computer interaction, then 3-4 telephone follow-up calls made to each participant.	assessment and feedback session.	
Green, 2014 (53)	RCT 6 months HTN: n=101	FTF and website (internet) Dietitian	*Materials and procedure:* Participants were provided with a scale, pedometer, and home BP monitor, and DASH education. After the visit, dietitians maintained communication with participants using secure online messaging. Participants were asked to share their self-monitoring data with the dietitian – dietitian responded to questions via this system and provided resources (e.g. recipes and websites) and encouraged participants to reach their goals. Weight loss was encouraged by substituting high calorie foods for fruits/vegetables, and general cooking advice. Dietitians met with the study team by phone every 2 weeks to review treatment plans and debrief. *Location:* community/ambulatory setting. *Dose and timing:* Participants shared self-monitoring data with the dietitian once a week for 2 months, every 2 weeks for 2 months, and then every month for 2 months.	Usual care, detail not defined	1. F+V (servings/day) 2. HbA1c (%) 3. TC (mmol/L) 4. LDL (mmol/L) 5. HDL (mmol/L) 6. SBP (mmHg) 7. DBP (mmHg) 8. Weight (kg)
Hawkes, 2012 (54)	RCT 6 months CHD:	Telephone Health professionals –	*Materials and procedure:* Participants were posted a ProActive Heart handbook outlining the program goals for CHD risk factors. The health coaching	Usual care (the educational resource ‘My	1. Vegetables (>5/day) 2. Fruits (>2/day) 3. Fat (<30% EEI)

Author, Year	Methods	Delivery method and provider	Telehealth intervention content	Comparator	Outcomes
	n=337	details NP	sessions were based on the current guidelines for CHD. The health coaching sessions included guiding participants through a series of steps beginning with an assessment of their CHD risk factor profile at the commencement of the program followed by feedback on their profile. Subsequent sessions included (a) introduction and identification of any cardiac symptom changes, (b) assessment and health coaching on relevant CHD risk factors, (c) follow-up on progress towards previous actions and goals, and (d) session review and action plan. *Location:* community/ambulatory setting. *Dose and timing:* The intervention commenced within the first 2 weeks of hospital discharge. Contact was made at a time convenient to the participant (up to ten telephone calls made lasting 30 minutes each) weekly for 3 weeks, fortnightly for 3 weeks, then monthly.	Heart My Life' and a quarterly information newsletter).	4. Saturated fat (<10% EEI) 5. Sodium (<2300mg/day) 6. PA (min/week)
Izquierdo, 2010 (60)	RCT 24 months T2DM: n=438	Videoconference Nurse and Dietitian	*Materials and procedure:* Medical nutrition therapy goals included improved glycaemic, blood pressure, and lipid control. Initial videoconference aimed to educate on self-management techniques and problem solving, before counselling with a dietitian. A document camera was used to review nutrition education materials, discuss home blood glucose patterns, and display food models and sample meal plans. Dietitian videoconferences were conducted to facilitate behaviour change and help formulate and	Usual care (American Diabetes Association Standards of Care practice guidelines)	1. Diet/exercise (combined **non-adherence** score) 2. BMI (kg/m^2) 3. WC (cm)

Author, Year	Methods	Delivery method and provider	Telehealth intervention content	Comparator	Outcomes
			review strategies. Weight loss was also encouraged, behaviour change goals (such as eat less carbohydrate, choose low fat foods, eliminate snacks) were set to achieve these goals. *Location:* community/ambulatory setting. *Dose and timing:* monthly videoconferences, and follow-up videoconference visits were scheduled with the dietitian every second month.		
Lear, 2014 (55)	RCT 16 months CVD; n=71	Internet Nurse, exercise specialists and dietitian delivered; Program designed by physicians and allied health professionals.	*Materials and procedure:* An online system directed participants to content for each week of the cardiac rehab program. One-one online chat sessions were used to discuss progress, symptoms, and give exercise prescription, and dietary recommendations, based on the Stages of Change and Behavioural Cognitive Theory. The patients also had access to the staff via email after these sessions. The dietary aspect to the intervention was individualised based on the participant's current diet and risk factors. The dietitian would ensure that the participant was eating sufficient protein, complex carbohydrates and healthy fats while emphasizing limitations on refined carbohydrates and fats. *Location:* community/ambulatory setting. *Dose and timing:* There was weekly education sessions in the form of interactive slide presentations, as well as monthly 'asks an expert' group chat sessions.	Usual care, detailed not defined	1. Fat (% calories) 2. Saturated fat (% calories) 3. SBP (mmHg) 4. DBP (mmHg) 5. TC (mmol/L) 6. LDL (mmol/L) 7. HDL (mmol/L) 8. Triglycerides (mmol/L) 9. WC (cm) 10. BMI (kg/m^2) 11. PA (calories/week)
McConnon,	RCT	Internet	*Materials and procedure:* Intervention followed	Continued to	1. Fruit (servings/week)

Author, Year	Methods	Delivery method and provider	Telehealth intervention content	Comparator	Outcomes
2007 (14)	12 Months Obesity; n= 131	(website) Informed by best practise guidelines	lifestyle guidelines in treating obesity, offering a combination of dietary advice, PA advice and behaviour therapy. The website was designed with tools and sections that provided this. Dietary education was to reduce calories by reducing fat and carbohydrates. Education on energy value of different foods; label reading, preparation and food purchase; adequate water intake; and limiting alcohol consumption. The website also offered personalized advice to participants, based on their responses to a series of online questions regarding eating and activity habits and current weight. Automatic e-mails were generated if participants did not visit the website regularly. *Location:* community/ambulatory setting. *Dose and timing:* Education provided at each logon to the website at the participant's discretion.	receive usual care; given printed information at baseline, typical of usual care.	2. Vegetables (servings/week) 3. Weight (kg) 4. PA (score)
Migneault, 2012 (40)	RCT 12 months HTN: n=337	Automated telephone Developed by indigenous health professionals – details NP	*Materials and procedure:* Participants received a manual describing HTN, dietary recommendations, recipes, and local resources for exercise, and provided information to support medication adherence. The first three calls introduced the 3 targeted behaviours and their role in BP control, and described the online system. Content of calls: (a) introduction, (b) reporting health measurements (pedometers, BP monitor, weight scales), (c) theory-based interactive education and counselling. The PA module aimed to increase levels of moderate-or-	Usual care, detail not defined	5. Diet quality score 6. PA (min/week) 7. SBP (mmHg) 8. DBP (mmHg)

Author, Year	Methods	Delivery method and provider	Telehealth intervention content	Comparator	Outcomes
			greater intensity PA. The diet module consisted of one overview call and two calls for each of four topics: fruits/vegetables, fibre, sodium, and fat. The content of these calls was designed to promote the DASH diet. Medication adherence was emphasised. *Location:* community/ambulatory setting. *Dose and timing:* The automated telephone intervention delivered one call/week for 32 weeks. The PA module consisted of 12 calls, the diet module consisted of nine calls, and the medication adherence module consisted of eight calls.		
Miller, 2016 (46)	RCT 8 weeks HTN n=123	FTF + telephone + online supermarket ordering Dietitian developed	*Materials and procedure:* Key aspects of the intervention were the DASH diet and included a $30/week allowance for the purchase of high-potassium foods from a provided list. Coaches discussed self-management and individual food preferences, including the DASH diet. Intervention participants choose from an extensive high K+ list of food that aimed to provide 17000mg/week K+. Coaches tailored education to food preferences, needs and assisted with online ordering when required. *Location:* In clinic and community setting and online ordering. *Dose and timing:* Participants received a 1 FTF session with a study coach who delivered a dietitian-developed module on the DASH diet followed by weekly 15-minute telephone calls.	Control – received DASH printed materials pre-baseline. Received $240 in total to spend at the same supermarket.	1. Fruit/vegetable (servings/day) 2. Fibre (g/day) 3. Fat (% calories/day) 4. Potassium (g/day) 5. SBP (mmHg) 6. DBP (mmHg) 7. TC (mg/dL) 8. LDL (mg/dL) 9. HDL (mg/dL) 10. TG (mg/dL) 11. Weight (kg)

Author, Year	Methods	Delivery method and provider	Telehealth intervention content	Comparator	Outcomes
Mok, 2013 (56)	PP 3 months CVD: n=82	FTF and telephone Nurse	*Materials and procedure:* Three elements to the intervention: F2F nurse consultation session, a self-management workbook, and telephone follow-ups. Participants reviewed their own dietary habits relevant to their CHD risk and made appropriate goals. Workbook: made by dietitians taking into account financial means, personal preference, and expected health benefits. A logbook was provided which contained mutually agreed dietary goals and an action plan treatment. Patients recorded their eating diary 3 times per week in the logbook (2 weekdays and 1 weekend). The telephone follow-up reviewed dietary modifications, problem-solving skills and provided reinforcement for positive changes that resulted. *Location:* Cardiac outpatient clinic and community setting *Dose and timing:* FTF: 30-minute face-to-face session was conducted by a cardiac nurse within 1 week after the dietary class in usual care. Telephone calls provided monthly.	Usual care and standard cardiac rehab, also attended a dietary class which was based on similar guidelines.	1. Saturated fat (score) 2. Salted and preserved food intake (score) 3. Heart healthy food intake (score) 4. TC (mg/dL) 5. LDL (mg/dL) 6. HDL (mg/dL) 7. TG (mg/dL)
Philipson, 2011 (42)	RCT 12 months HF: n=97	FTF and telephone Nurse and dietitian	*Materials and procedure:* The dietary recommendations were individualized to cultural, economic, and social habits, and based on the results of a 24 h dietary recall and FFQ. Patients were encouraged to ask questions about their food choices, cooking, and how to cope with fluid (restricted to 1.5L/day) and salt restrictions (to 2-	Received minor dietary advice from a nurse.	1. Urinary sodium (mmol/L) 2. Urinary potassium (mmol/L) 3. Weight (kg) 4. BMI (kg/m^2)

Author, Year	Methods	Delivery method and provider	Telehealth intervention content	Comparator	Outcomes
			3g/day). Patients were contacted by telephone after 10–12 months by a dietitian without prior announcement. *Location:* Follow-ups were performed at a home visit with the study nurse after 4 weeks and by telephone, without prior announcement in the ambulatory setting. *Dose and timing:* Follow-ups were performed at a visit with the study nurse after 4 weeks and by telephone, without prior announcement, by the dietitian or the specially trained nurse every 2–3 weeks.		
Sone, 2010 (61)	RCT 8 years T2DM: n=1304	FTF and telephone Nurses, dietitians and psychotherapists	*Materials and procedure:* Dietary advice was provided by an dietitian using the 'Food Exchange Lists Dietary Guidance for Persons with Diabetes' and included individual counselling on dietary habits, PA and adherence to medications. Participants tracked lab values for feedback and therapeutic results. Goals were set for patients in the intervention group and their physicians: i.e. HbA1c level <6.5%; BMI <22 kg/m2; BP <140/85 mmHg; serum TC level <5.72 mmol/l; serum TG level <1.65 mmol/l; serum HDL cholesterol >1.04 mmol/l; WHR <0.9 for men and <0.8 for women; smoking cessation; and abstinence from alcohol. Participants identified as having poor control or not ideal results during the study were sent additional educational material.	Regular specialists' care was provided throughout the study period and patients were treated as they were before the study started.	1. Energy (KJ) 2. Fat intake (grams) 3. HbA1c (%) 4. BMI (kg/m^2) 5. SBP (mmHg) 6. DBP (mmHg) 7. TC (mmol/L) 8. HDL (mmol/L) 9. TG (mmol/L) 10. PA (Baecks score)

Author, Year	Methods	Delivery method and provider	Telehealth intervention content	Comparator	Outcomes
			Location: Outpatient centres and ambulatory setting. *Dose and timing:* Regular outpatient visits, with fortnightly telephone calls. Additional counselling sessions were also encouraged at any convenient time, depending on the needs of patients.		
Welch, 2013 (45)	RCT 8 weeks HD: n=44	PDA Nurse, delivered by research assistants	*Materials and procedure:* The electronic dietary self-monitoring application provided individualized information to assist patients with dietary and fluid self-monitoring. A feedback screen displayed participants' intake in relation to their dietary prescriptions. Participants scan food barcodes –app checks if the scanned food complies with their diet recommendations. A 24-hour telephone number was provided in case participants had questions or problems with the application at home. *Location:* Dialysis clinics and ambulatory setting. *Dose and timing:* Participants entered data daily. Research assistants would provide extra education as needed throughout the intervention and met with participants at each dialysis session to download the intake data during the intervention period.	Control group – same time spent using the app – but only monitoring PA. – received the same training and process as intervention just without diet intervention	1. Diet self-efficacy (score) 2. Fluid self-efficacy (score)
Woollard, 1995 (57)	RCT 18 weeks HTN: n=100	Telephone Nurse	*Materials and procedure*: Participants were counselled using a stage of change behavioural model and motivational interviewing with the aim of: (a) Weight reduction following the Australian Nutrition Foundation guidelines. (b) In drinkers a reduction in alcohol intake to 1 standard drink a day	Usual care, detail not defined	1. Urinary sodium (mmol/L) 2. Weight (kg) 3. SBP (mmHg) 4. DBP (mmHg)

Author, Year	Methods	Delivery method and provider	Telehealth intervention content	Comparator	Outcomes
			(10 g) for women and 2 standard drinks daily (20 g) for men. (c) Salt restriction to less than 90mmol/day. (d) Less than 30% daily energy dietary fat with restriction of saturated fat intake to 10%. (e) An increase in regular PA. (f) Smoking cessation. *Location:* community/ambulatory setting. *Dose and timing:* Received 1 FTF appointment receiving initial results and then five telephone counselling sessions lasting 15 min.		
Woollard, 2003 (63)	RCT 12 months CVD or T2DM: n= 138	Telephone Nurse	*Materials and procedure:* The program aimed to control weight, increase PA, nutrition advice to reduce fat and salt intake and increase fibre consumption, moderate alcohol intake and achieve cessation of smoking using principles from transtheoretical model, motivational interviewing, and self-efficacy. *Location:* community/ambulatory setting. *Dose and timing:* Received 1 FTF counselling session and telephone (10–15 min consultations) every month. The high level intervention group were counselled in individual sessions up to 60 min every month.	The control group were offered Heart Foundation health promotion literature and remained under the care of the general practitioner and had no further intervention.	1. Energy (KJ) 2. Total fat (% EEI) 3. Saturated fat (% EEI) 4. Sodium (grams) 5. Weight (kg) 6. BMI (kg/m^2) 7. WC (cm) 8. TC (mmol/L) 9. LDL (mmol/L) 10. HDL(mmol/L) 11. TG (mmol/L)
Wong, 2010 (62)	RCT 13 weeks CAPD; n=98	Telephone Nurse	*Materials and procedure:* Telephone calls were guided by a structured format: (a) overall health condition; (b) monitoring changes from the specific health concerns identified in the previous interaction, monitoring progress, providing health	Usual care (instruction on medication and general health advice)	1. Diet **Non- adherence** days (5-point Likert scale) 2. Fluid **Non-adherence** days (5-point Likert

Author, Year	Methods	Delivery method and provider	Telehealth intervention content	Comparator	Outcomes
			advice, reinforcing health self-management behaviours, and assessing the need for referral; (c) reviewing and setting mutual health goals; (d) arranging next call. Follow-up calls reinforced behaviours and identified potential complications and needs, and reviewed the mutual goal-setting. A renal nurse made the final call to review the health goals with the patient and provided advice if needed. *Location:* community/ambulatory setting. *Dose and timing:* Prior to discharge a renal nurse conducted an initial assessment with participants and provided health education. The first call then occurred 72 hours after discharged. There was no set time limit for each call. General nurses made subsequent calls every week for 4 weeks.		scale)

[1] BP, Blood pressure; SBP, Systolic blood pressure; DBP, Diastolic blood pressure; BMI, Body mass index; CVD, Cardiovascular disease; SEM, Standard error of the mean; TC, Total cholesterol; HF, Heart failure; CHF, Congestive heart failure; BGL, Blood glucose level; PA, Physical activity; ADA, American Diabetes Association; MDT, Multi-disciplinary team; SMS, Short message service; DM, Diabetes mellitus; HTN, Hypertension; TC, Total cholesterol; LDL, Low-density lipoprotein; HDL, High-density lipoprotein; TG, Triglycerides; WC, Waist circumference; FTF, Face-to-face; %, percent; EEI, Estimated energy intake; HbA1C, Glycosylated haemoglobin; T2DM, Type 2 diabetes mellitus; ACM, All-cause mortality; DASH, Dietary approaches to stop hypertension; CHD, Coronary heart disease; K+, Potassium; FFQ, Food-frequency questionnaire; WHR, Waist-hip ratio; PDA, Personal digital assistant; PP, Pre-post-test designed study.

5.5.2.4 Measures of dietary sodium intake

A total of seven studies measured dietary sodium intake. Five studies were pooled (total of 570 participants) (42, 50, 56, 57, 63) showing telehealth intervention reduced dietary sodium intake on urinary and/or self-assessed scores (SMD -0.39 [95% CI: -0.58, -0.20];p=0.0001; I^2=19%) compared to non-telehealth interventions (Figure 5-2). All seven studies used the telephone as the telehealth delivery method and were conducted in CVD. Two studies used non-validated tools for determining daily sodium intake, measuring teaspoons of salt (1 teaspoon being approx. 6 g of sodium chloride or 2300mg sodium) (50) and a salted food score (56). Exclusion of these studies from the analysis left 3 studies reporting on mmol/L of urinary sodium per day (42, 57, 63), which did not reach significance (MD -8.27mmol [95% CI: -17.34, 0.79];p=0.07;I^2=24%). Two studies were unable to be pooled statistically and are reported in Table 5-2. The results remained significant in two trials with 12 month (42, 63) follow-up (MD -6.00 [95% CI: -10.41, -1.59; p=0.008; I^2= 0%].

5.5.2.5 Energy intake

A total of three studies (total of 2172 participants) measured energy intake (59, 61, 63) all with long-term durations (12 months to four years). Telehealth intervention did not significantly reduce energy intake (MD -10.48 kcal [95% CI: -67.20, 46.25];p=0.72; I^2=15%) compared to usual care. All three studies used the telephone as the telehealth delivery method and were conducted in participants with diabetes.

5.5.2.6 Sources of dietary fat intake

A total of eight studies reported on measures of dietary fat intake (13, 44, 46, 54-56, 61, 63) including total fat per day (13, 61, 63), percent calories from total fat (55), saturated fat intake per day (13, 56, 63), percent calories from saturated fat (55), and the Kristal Fat and Fibre Behavior Scale (44). Telehealth intervention did not significantly reduce total dietary fat intake (MD -0.10g [95% CI: -1.90, 1.70]; p=0.91; I^2=76%) in four studies (2427 participants), but did significantly reduce saturated fat compared to non-telehealth comparators (MD -0.93g [95% CI: -1.51, -0.32]; p=0.002; I^2=0%) in two studies (572 participants). Three studies were unable to be pooled statistically and are reported in Table 5-2. Long term trials (durations 12 months to four years) were not significant (55, 61, 63).

5.5.3 Telehealth dietary intervention and clinical outcomes

Twenty one studies measured clinical outcomes which were able to be pooled into meta-analysis.

5.5.3.1 Blood pressure

Telehealth intervention significantly reduced SBP by MD -2.64 [95% CI: -5.12, -0.16]; p=0.04; I^2= 83% in 12 studies with a median duration of 6 months (total of 4202 participants) (40, 41, 46, 48-51, 53, 55, 57, 59, 61) (Figure 5-4). A subgroup analysis by chronic disease condition showed the result for SBP was more pronounced in people with diabetes (59, 61) (MD -5.91mmHg [95% CI: -11.14, -0.68]; p=0.03; I^2= 69%), than in people with CVD (40, 41, 46, 48-51, 53, 57) (MD -1.31mmHg [95% CI: -3.39, 0.77]; p=0.22; I^2= 60%). Diastolic BP was not significantly reduced following telehealth intervention (MD -1.60mmHg [95% CI: -3.42, 0.22;p=0.1; I^2= 87%] in 10 studies (encompassing 3512 participants) (46, 48-51, 53, 55, 57, 59, 61). Subgroup analysis by chronic disease condition did not alter the result for diastolic BP (data not shown). Four long term trials (durations 12 to 24 months) did not result in a significant change in both systolic and diastolic BP (40, 55, 59, 61).

5.5.3.2 Weight, BMI and waist circumference

Weight was significantly reduced by dietary telehealth intervention (MD -0.80kg [95% CI: -1.61, 0]; p=0.05; I^2= 79%) in eight studies encompassing 974 participants (14, 42, 44, 46, 53, 57, 59, 63) (Figure 5-4). Seven studies reported non-significant changes in BMI (data not shown) in 3560 participants (14, 42, 50, 51, 54, 55, 60, 61, 63) and five studies reported a significant reduction in waist circumference in 1659 participants (49, 55, 59, 60, 63) of MD -2.08 [95% CI: -3.97, -0.20]; p=0.03; I^2=84% (Figure 5-4). BMI and weight were not significantly changed in longer term studies, however, waist circumference remained significant in four trials with durations 12 months to 24 months (55, 59, 60, 63) MD -0.51 [95% CI: -0.73, -0.29]; p=0.0001; I^2=0%.

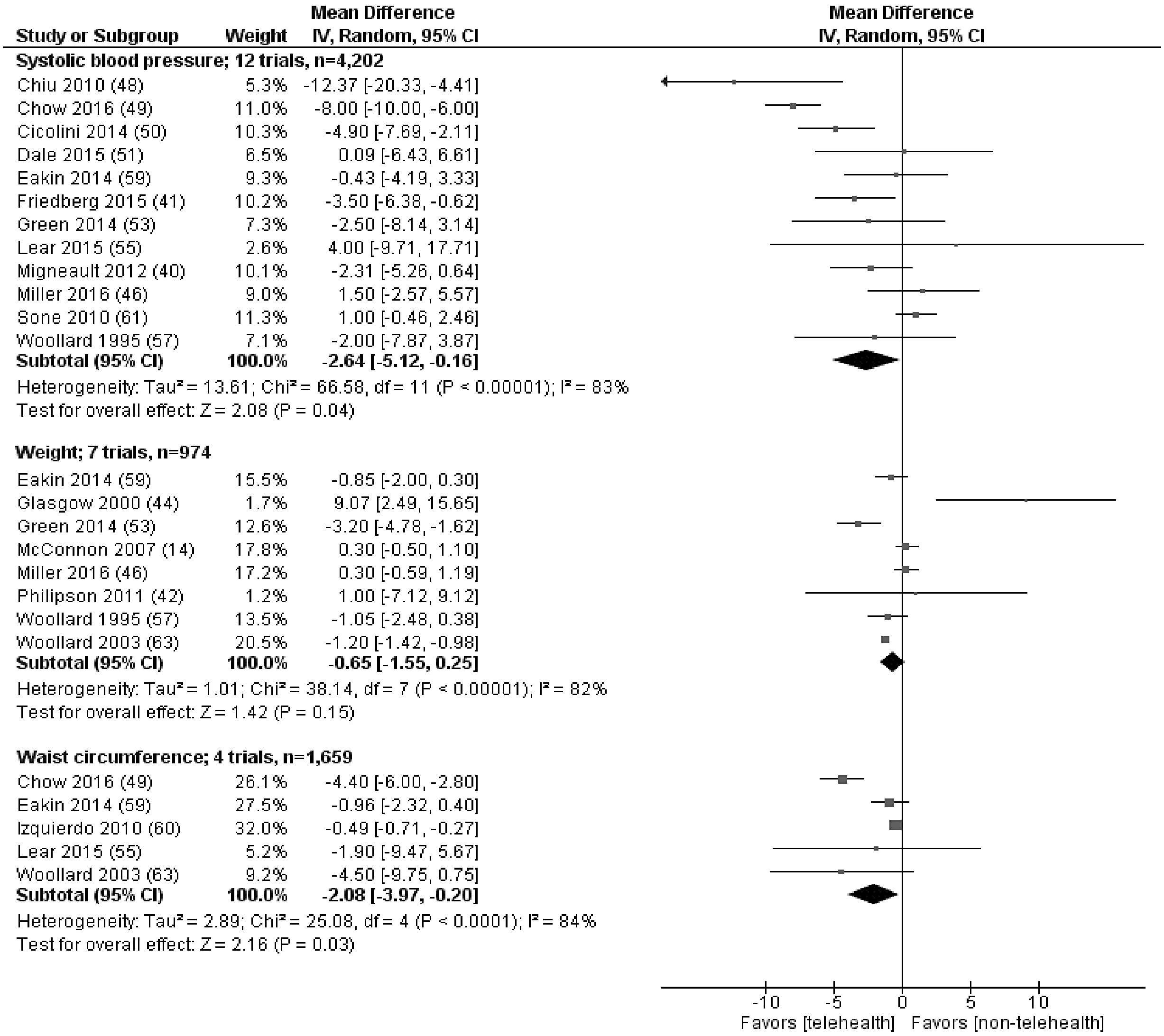

Figure 5-4: Effects of telehealth dietary interventions on systolic blood pressure (mmHg), weight (kg) and waist circumference (cm). The mean and SD of changes from baseline are reported for trials. Effects of trials are presented as weight (%) and mean difference (95% CI).

5.5.3.3 Serum lipids and HbA1c

Changes in serum lipids and HbA1c were reported in 11 studies. Telehealth intervention significantly reduced total cholesterol (44, 46, 49-51, 53, 55, 56, 59, 61, 63) in 11 studies of 3697 participants (MD -0.08 mmol/L [95% CI: -0.16, -0.00]; p=0.04; I^2=52%) (Figure 5-5). No changes in LDL (49-51, 53, 56, 59, 63), HDL cholesterol (49, 51, 53, 56, 59, 63), or HbA1c (44, 59, 61) were observed (data not shown). Triglycerides were significantly reduced following dietary telehealth intervention compared with usual care (MD -0.10 mmol/L [95% CI: -0.19, -0.01];p=0.04; I^2= 70%) in seven studies encompassing 3268 participants (46, 49, 50, 56, 59, 61, 63) (Figure 5-5). Sensitivity analysis excluding durations ≥2 years follow up (2 studies), of 2 (59) and 8 (61) years reduced the heterogeneity and gave a MD -0.16 mmol/L

[95% CI: -0.26, -0.06]; p=0.001; I^2=39%. Long term trials (durations 12 months to four years) did not result in significant change in biochemical outcomes (55, 59, 61, 63).

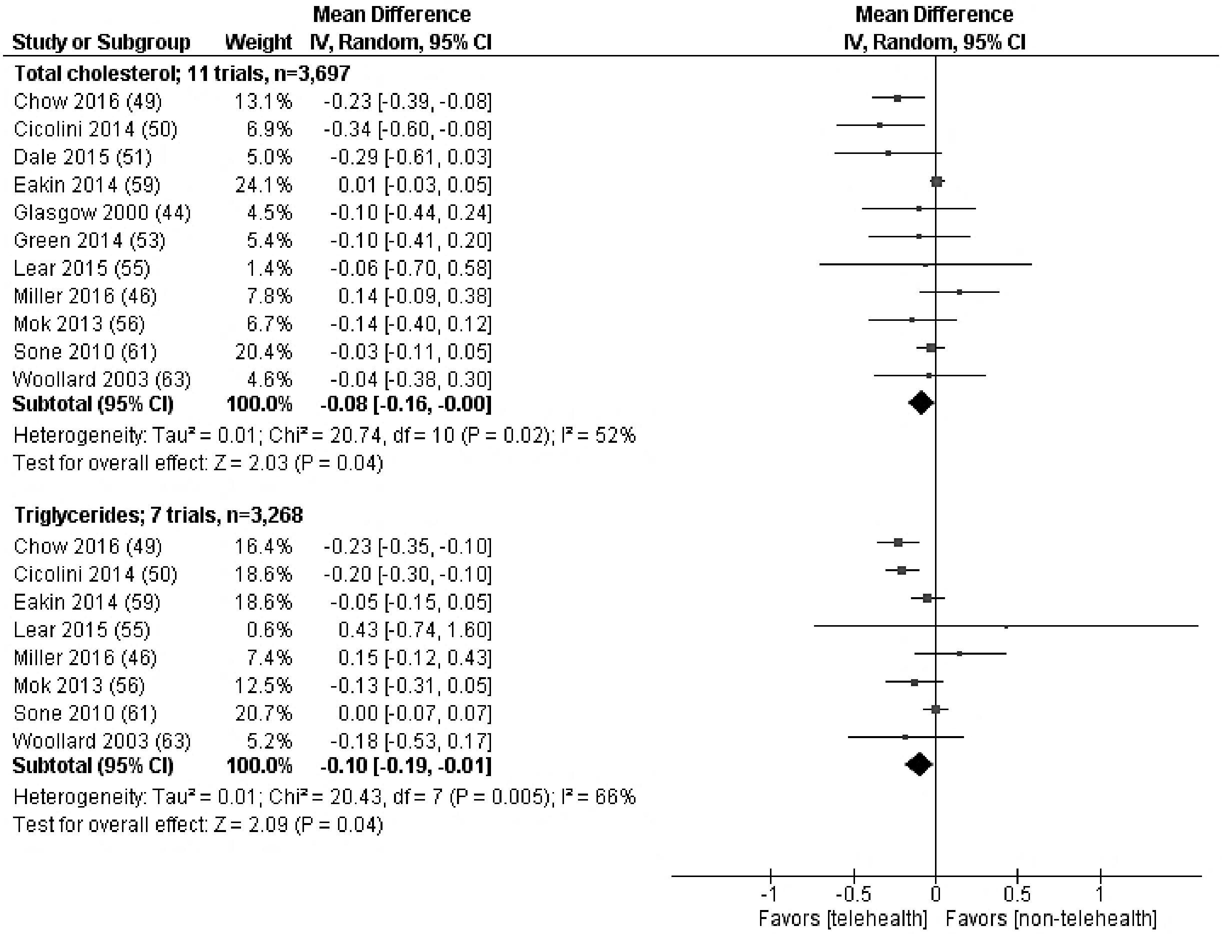

Figure 5-5: Effects of telehealth dietary interventions on total cholesterol and triglycerides (mmol/L). The mean and SD of changes from baseline are reported for trials. Effects of trials are presented as weight (%) and mean difference (95% CI).

5.5.3.4 Mortality and hospitalisations

Two studies reported clinical endpoints and rates of hospitalisations (47, 52). Ferrante and colleagues (52) conducted a 16 month telephone intervention in heart failure patients with contacts determined by severity of condition. The study was assessed as a low risk of bias and lead to significantly reduced all-cause mortality in the telehealth group (15.3%) compared to usual care (16.1%; $p<0.05$), heart failure (HF) admission (16.8% and 22.3%, respectively; $p<0.005$), CV admission (24.1% and 30.1%, respectively; $p<0.006$), and all-cause admission (34.3% and 39.1%, respectively; $p<0.05$). However in the study by Albert et al (47) a three month multifactorial lifestyle video and telephone based intervention in HF did not significantly reduce rates of HF hospitalisations between groups, and was a moderate risk of bias study.

Table 5-2: Results for dietary outcomes unable to be pooled into meta-analysis

Author, Year	**Chronic disease**	**Telehealth method**	**Results** *Telehealth versus control*
Dietary adherence measures			
Arora, 2013 (58)	DM	Telephone	↑ 0.31 points (SDSCA)
Chiu, 2010 (48)	HTN	Telephone	↑ 1 point (diet adherence score)[2]
Ferrante, 2010 (52)	CVD	Telephone	↑ 44.7% (dietary adherence score)[2]
Izquierdo, 2010 (60)	DM	Videoconference	↑ 2.64 points (dietary adherence score)
Mok,2013 (56)	CVD	Mobile (SMS)	↑ 1.69 points[2] (Chinese Eating Habit Assessment Questionnaire)
Welch, 2013 (45)	ESKD	PDA	↑ 4.4 points (The Cardiac Diet Self-Efficacy Instrument)
Wong, 2010 (62)	ESKD	Telephone	↑ 0.71 points[2]
Fruit and Vegetables measures			
Dale, 2015 (51)	CVD	Mobile (SMS)	↑ 28% of participants consuming >5 servings of fruit and/or vegetables per day[2]
Hawkes, 2013 (54)	CVD	Telephone	↑ 8.6% participants consuming >5 servings of vegetables per day[2]
Hawkes, 2013 (54)	CVD	Telephone	↑ 4.9% participants consuming >2 servings of fruit per day
Glasgow, 2000 (44)	DM	Telephone	↑ 0.2 points
Dietary sodium measures			
Albert, 2007 (47)	CVD	Video	↓ 11% of participants not adhering to a sodium reduced diet[2]
Hawkes, 2013 (54)	CVD	Telephone	↓ 0.3% participants consuming <2300mg sodium per day
Welch, 2013 (45)	ESKD	PDA	↑ 0.6 points (perceived benefits of sodium adherence)
Dietary fat measures			
Hawkes, 2013 (54)	CVD	Telephone	↑ 3% of participants consuming >30% energy from fat per day

Author, Year	Chronic disease	Telehealth method	Results *Telehealth versus control*
Lear, 2015 (55)	CVD	Internet	↓ 0.48% energy from saturated fat intake[2]
Lear, 2015 (55)	CVD	Internet	↓ 0.29% energy from total fat intake
Glasgow, 2000 (44)	DM	Telephone	↑ 0.25 points
Mok,2013 (56)	CVD	Mobile (SMS)	↓ 3.09 points[2]

[1] Abbreviations: DM, Diabetes mellitus; CVD, Cardiovascular disease; HTN, hypertension; ESKD, end-stage kidney disease; SMS, short message service; PDA, personal digital assistant; SDSCA, Summary of Diabetes Self-care Activities; mg, milligrams. [2] Results were statistically significant.

5.5.4 Risk of bias

Figure 5-6 shows the risk of bias of the included studies. Risk of bias was low to moderate across the included studies. The majority (92%) of studies had adequate randomization; however concealed allocation was only reported in 48% of the included studies suggesting potential selection bias. Double blinding was only achieved in one study (49), and blinding of participants to treatment arm only was done in one study (41) however intervention staff were aware of treatment allocation. All other trials were unable to blind participants given the nature of dietary intervention to facilitate and modify behavior change. However this means that detection bias was high in 80% of the dietary measures as they were self-reported. Attrition bias (through high loss to follow-up and no explanation of how such data were dealt with) was judged as high in 32% of studies. Furthermore there appears to be reporting bias in at least 20% of the included studies as they did not report outcomes which were stated in methods or protocol papers; six were rectified upon contact to corresponding authors. When GRADE (directness, precision, consistency, and study limitations) recommendations were considered, the evidence quality for diet quality and fruit and vegetables intake was considered moderate given the dietary intake data was all self-reported.

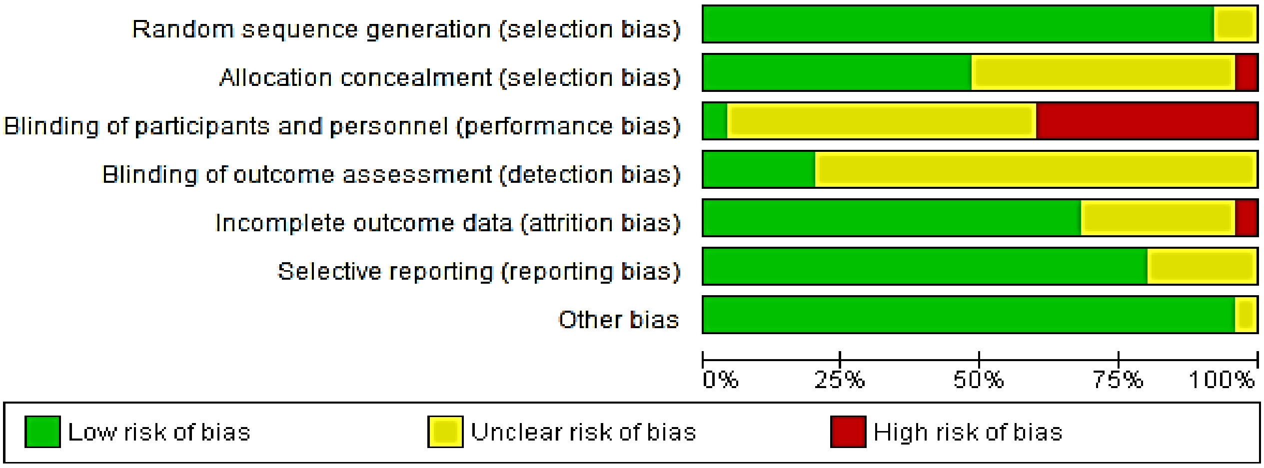

Figure 5-6: Risk of bias across the included studies showing the summary percentage in each domain.

5.6 Discussion

This systematic review assessed the effectiveness of complex telehealth dietary interventions for facilitating dietary change in adults with chronic disease. The primary finding was that dietary interventions delivered by telehealth effectively improved dietary adherence on a moderate scale, and small improvements in diet quality (38). Single macronutrients were less likely to be modified by telehealth intervention, including energy and total dietary fat intake which were not significantly different between groups in the pooled analysis.

Telehealth intervention resulted in significant reduction in dietary sodium intake compared with non-telehealth interventions (SMD -0.39;p=0.0001) which is considered a moderate effect statistically (38). All dietary sodium outcomes showed improved compliance to a reduced sodium intervention using telehealth, which has clinical implications for telehealth as it may provide a useful tool in future intervention studies given sodium modification is hampered by poor compliance in clinical practice (64). The finding that fruit and vegetables increased by one serving per day following telehealth intervention support the potential for the use of telehealth to improve diet quality, which is a similar finding to a previous systematic review in telephone based interventions in the general population (65). Although significant heterogeneity was observed, sub-analysis by type of technology reduced the effect size to 0.8 servings, but remained significant. Fruit and vegetable consumption is a strong predictor of mortality, and the magnitude of change we found may reduce the risk of all-cause mortality (66). The EPIC-Heart study estimated that an increase in every 80g portion of fruit and vegetables was associated with a 4% reduction in risk of death (67).

Whole-of-diet approaches, as opposed to isolated single nutrients interventions, reflect how foods within the diet are consumed, and have an impact on other nutrients when manipulated (for example a change to fat intake will often result in a concomitant increase in the proportion of energy derived from carbohydrate). Developments in nutrition science recognize the complexity of foods consumed in combination on long-term CVD risk, weight regulation, and disease progression (68). Such approaches appreciate the interaction of foods and nutrients which may be more relevant to chronic disease when examining the cumulative effect of food on health over time (69, 70). This shift in nutrition focus suggests single nutrient interventions will become less utilised clinically and in public health practice (68), which is an important consideration for emerging telehealth interventions in the design of dietary educational content. Although we observed only small changes in diet quality, the magnitude of change demonstrated may result in a large public health benefit if adopted for secondary prevention of chronic disease (71). For example a higher diet quality has been linked to a reduced risk of all-cause mortality in people aged over 65 years (72). Although a stronger association was found when comparing the highest to the lowest quartiles, the risk reduces at each quartile above the lowest diet quality (72). Furthermore, if improving fruit and vegetable intake to better reflect dietary guidelines and therefore overall dietary quality, this may reduce the complications of chronic disease (33), which has been demonstrated to result in a reduction in all-cause mortality of 21% over a 15 year follow-up period (73).

Dietary change through telehealth interventions can translate to small improvements in some clinical outcomes, such as a reduction in SBP of 3mmHg. Although this is slightly less than larger scale meta-analysis of all dietary sodium interventions in hypertension of -5mmHg, the effect size is similar to people without hypertension (74). A sustained change in SBP of 2-3mmHg over a period greater than 6 months has been suggested to translate into a reduced risk of cardiovascular events (75). Other risk factors such as weight, waist circumference, total cholesterol and triglycerides improved significantly in some studies following telehealth intervention, whereas LDL, HDL and HbA1c did not. The long term studies (>12 months) included were not adequately powered to detect BP and weight change at final follow up, and the inclusion criteria meant some larger trials were excluded due to the lack of reporting of diet outcomes. For example, the POWER study (76) observed a between group change in SBP of -1.8mmHg and weight change of -4kg after 24 months in the telephone coaching group but was not able to be included. This well-designed trial supports the effects of telehealth on surrogate CVD outcomes in chronic disease.

A previous systematic review demonstrated technologies such as telephone and video contact improved adherence to diet (31), which we have now extended to improved dietary quality, fruit/vegetable intake and reduction in sodium intake when compared to usual chronic disease care. Telehealth may facilitate compliance to diet via a variety of mechanisms beyond the provision of regular review and behavior prompting, although it is likely the most influential to sustained dietary change in our review (9, 77). Telehealth strategies offer feasible ways to facilitate dietary changes, and have advantages over FTF consultations, including flexibility (78) and a high rate of patient acceptability (20, 79). Smart phones are used by over 75% of the population (80, 81), highlighting the widespread potential telehealth methods provide to improve access, coverage, and implantation methods, particularly in low socio-economic populations (24). As primary healthcare may hold the key to the dissemination of telehealth dietary delivery methods, evaluation studies are needed. Process evaluation frameworks should be incorporated into future telehealth trials, reporting attendance/participation, acceptability and costs, which will ultimately assist their translation into clinical practice (82).

This study is the first systematic review of telehealth strategies for facilitating multifactorial dietary change. Further strengths were: the comprehensive search strategy used, the use of two independent review authors throughout the review, and the use of Cochrane methodology to appraise the risk of bias. The TIDieR checklist (37) was used to extract data, allowing multiple sources of heterogeneity and intervention reporting inadequacies to be identified.

There are several limitations of the review, including that multifaceted dietary changes were usually a component to multiple lifestyle recommendations (22 of the 25 included studies), making it difficult to delineate the effect of isolated dietary intervention on clinical outcomes. Half the included studies utilized telephone delivery methods, with other telehealth technologies, such as smart phone applications and internet use are underrepresented, and may reduce the generalizability of the findings.

This review highlights the need for future trials that aim to change dietary behavior using telehealth strategies other than telephone – such as mobile, internet or videoconference methods. The application of the TIDieR checklist highlights a need for better reporting of telehealth interventions, as many trials did not report important logistical data relating to intervention conduct. Finally, although favourable changes were reported in some surrogate clinical outcomes such as blood pressure and lipid profiles following telehealth intervention, this may not translate to hard clinical endpoints. Due to a lack of studies, conclusions cannot be drawn about effects on mortality and hospitalisations. Future well-designed intervention studies with adequate length of follow up are required to assess these important end-points.

In conclusion, adults with a diet-related chronic disease may experience improvements in diet quality, fruit and vegetable intake, and dietary sodium intake if provided with dietary intervention using telehealth. While large variations in findings may be explained by differences in intervention conduct, it is difficult to explore due to suboptimal reporting of dietary interventions. Single macronutrients (calories and total dietary fat) were not significantly modified following telehealth intervention, which may highlight the benefit of delivering complex dietary intervention that target the quality of the diet and/or dietary patterns facilitated by convenient telehealth technologies. The results of this review support the changes in nutrient focus and may inform the future development of evidence-based telehealth programs, which ideally can be tailored to specific chronic disease conditions.

5.7 Author contributions

JK assisted in the conceptualisation of the review, conducted the initial literature search, assessed the risk of bias, conducted the analysis, drafted the manuscript and had primary responsibility for final content. KC conceived the review, conducted the literature search, risk of bias, assisted in analysis interpretation and revised the drafted manuscript. DR assisted in the conceptualisation of the review, interpretation, revised the drafted manuscript. TH participated in the design of the study and provided methodological and clinical expertise, and reviewed the drafted manuscript. All authors read and approved the final manuscript.

5.8 Competing interests

None declared.

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Chapter 6 - Patient experiences of dietary management in chronic kidney disease: A focus group study

6.1 Preface

The primary finding of Chapter 5 was that telehealth methods are effective at facilitating complex dietary change in chronic disease. However, Chapter 5 could only identify two dialysis studies in the ESKD population and found no eligible study conducted in people with CKD. To understand whether other technologies, such as the internet and mobile phones are suitable delivery methods for dietary education in CKD, patient engagement was required.

Chapter 6 details a patient engagement project which utilised focus groups to collect data about CKD patients' perspectives of their dietary recommendations, and the use of technology to support their self-management. The premise of this project was to engage people with CKD in the co-creation of a telehealth program which was patient-centred and structured specifically to overcome their biggest challenges to adhering to a healthy diet.

Informing this chapter was a state-wide cross-sectional survey (Appendix C), which was conducted to identify the potential for using the mobile phone and internet in CKD populations. This survey found that the mobile phone and internet were used by over 88% of people with CKD. Of the entire sample, 60% had a preference for telehealth-delivered dietary support. What remained to be answered, however, was how telehealth can be used to improve dietary intervention delivery, and what are the challenges that patients identify to making dietary changes. Therefore, Chapter 6 was designed, specifically to address thesis research questions 3 and 4.

This chapter contains the accepted version of an original manuscript published in the peer-reviewed journal *The Journal of Renal Nutrition*. The paper formatting has been modified in accordance with a consistent thesis style. However, the grammar, headings, and references (in-text and bibliography) are unaltered in accordance with the journal publishing guidelines.

Citation: **Kelly JT**, Campbell KL, Hoffmann TC, Reidlinger DP. Patient experiences of dietary management in chronic kidney disease: A focus group study. *Journal of Renal Nutrition*. 2017 [In-Press]

6.1.1 Related work to this Chapter completed by the candidate

One other manuscript relating to this chapter has also been published by the candidate, in the form of a (cross-sectional) original research article. While this paper is not a primary publication within this thesis, the candidate was involved in the ethics application, data collection and analysis, with the findings being directly related to the research question this chapter addresses, and is available in Appendix C. Specifically, the relevant focus of the paper to this chapter is the patient-engagement aspect determining what technology people with CKD are willing to use, and what the barriers to technology use may be.

- Bonner A, Gillespie K, Campbell KL, Corones-Watkins K, Hayes B, Harvie B, **Kelly JT**, Havas, K. Evaluating the prevalence and opportunity for technology use in chronic kidney disease patients: A cross-sectional study. *BMC Nephrology.* 2018; 19(1): 28.

6.2 Abstract

6.2.1 Objective

People with chronic kidney disease (CKD) contend with complex dietary recommendations. The challenge in practice is for clinicians to provide individualized support with the frequency and consistency required to sustain dietary changes. This study aimed to describe the experiences of patients with managing dietary recommendations, including their perspectives on the potential to use telehealth to support dietary management in CKD.

6.2.2 Design

Focus group study.

6.2.3 Setting

Two nephrology units in Queensland, Australia.

6.2.4 Subjects

21 adult patients with CKD (non-dialysis) and 3 caregivers (total N=24) purposively sampled to achieve diverse demographic and clinical characteristics.

6.2.5 Methods

Five focus groups were conducted, audio recorded and transcribed. Transcripts were analyzed using thematic analysis drawing on the principles of grounded theory.

6.2.6 Main outcome measure

Themes aligned with the research question.

6.2.7 Results

We identified five themes: exasperating stagnancy (patronized by redundant advice, confused and unprepared for dietary change, inevitability of failure, and barriers to accessing dietetic services); supporting and sustaining change (receiving regular feedback, incremental and comprehendible modification, practical guidance on food, flexibility in monitoring schedule, and valuing peer advice); fostering ownership (seeking kidney diet information, enacting behaviour change, making reminders, and tracking progress against targets); motivators and positive learning instruction (relying on reassurance, positive reinforcement, focusing on allowable foods, and involving family); threats and ambiguities of risk (sugar as the culprit, ubiquity of salt, illegible food labelling, avoiding processed foods, and questioning credibility of sources).

6.2.8 Conclusions

Patients with CKD desire a preventative approach to CKD progression and maintaining their health however are stymied by dietary restrictions and a lack of reliable dietetic advice. Easy-to-use telehealth options have the potential to overcome the shortcomings in current health service delivery which may be limiting factors to providing these approaches. They provide patients with pragmatic tools, comprehensible and consistent information which fosters ownership and self-monitoring.

6.2.9 Keywords

Diet; nutrition; chronic kidney disease; technology; focus groups; patient-centered care

6.3 Background

Diet has long been considered a modifiable risk factor for chronic kidney disease (CKD), with poor dietary habits representing a key modifiable risk factor for CKD progression.[1] Historically, dietary guidelines for CKD advise the restriction of individual nutrients, such as protein, sodium, phosphate and potassium.[2] However, these guidelines have been criticized because they are difficult to achieve,[3] and are underpinned by limited evidence for effectiveness in preventing important clinical complications including cardiovascular disease and progression to end-stage kidney disease (ESKD).[4-7]

Dietary advice is often multifaceted, complex and requires individualized support.[8,9] Dietary and fluid restrictions can be disorienting, overwhelming, and an intense burden for patients across all stages of CKD.[3] The majority of dietary interventions for pre-dialysis patients are one-off dietary education sessions, without ongoing follow up.[10] In contrast, regular interaction has been shown to be a key strategy for self-management and highly valued by people with CKD.[3] This mismatch in patients' needs and current clinical service provision highlights a pressing need to consider alternative strategies to support dietary change. Emerging evidence suggests that use of technology such as telehealth is effective in promoting dietary adherence,[11,12] and has the potential to meet rising service demands.[13] Telehealth modalities may provide an alternative framework for frequent and structured contact that is needed to support the complex dietary change required in CKD.

There is growing recognition of the value of patient engagement in healthcare provision, and the need to focus on their experience of services, to improve efficiency and 'patient-centered care'.[14] However, as far as we are aware, no study to date has focused on exploring pre-dialysis patients' experiences of receiving CKD dietary advice, nor their preferred service modalities for accessing current healthcare services. This approach might help in the development of patient-centered interventions. The aim of this study was to describe experiences of patients with CKD in managing dietary recommendations, including their perspectives on the potential to use technology to support dietary management.

6.4 Materials and methods

6.4.1 Participant selection

Participants with CKD were recruited from two nephrology units from an urban hospital outpatient service in Queensland, Australia. Eligible participants were adults aged 18 or over, had access to a mobile phone or the internet, were able to understand and speak English, not receiving dialysis treatment with CKD stage 3-4 (eGFR 15-60mL/min) and including long term-post transplant (Stage 5T).[15] Long term post-transplant patients, who had a stable GFR which met our inclusion criteria were deemed eligible on the premise that their dietary management is similar as per current best-practice guidelines.[16] Patients with a cognitive impairment who were unable to provide informed consent were excluded. Participants were purposively sampled to achieve diverse demographic (age, gender, and socio-demographic status) and clinical characteristics (time since diagnosis and comorbidities). Caregivers were not excluded from attending where requested by the participant in recognition of their key role in supporting the individual to self-manage and the potential insights they might provide to the research question. Participation was voluntary and written informed consent was obtained from patients and caregivers. All participants were provided with a retail gift voucher (AU$50) to acknowledge their time. Ethical approval was granted by the **(blind)** Gold Coast University Hospital and Bond University Human Research Ethics Committees.

6.4.1.1 Data Collection

The focus group guide was based on a review of the literature relating to patient experience of dietary change, and use of telehealth for dietary change (Appendix I). We also included visual prompts to stimulate in-depth discussion, including an introduction to telehealth methods to all groups using photos (of interactions between patient and clinician) of telephone consultation, text messages and email communication, online workshops and videoconferencing. We also showed a YouTube video to demonstrate an example of a telehealth intervention.[17] No real life examples were used in our study, and all telehealth examples discussed were hypothetical. Prior to study commencement, the topic guide was piloted with three hemodialysis patients whose results were not included in the analysis, and only used to test the depth, understanding and flow of questions. The focus groups were approximately two hours duration and conducted in a private meeting room, which provided a confidential environment. They were facilitated by the lead investigator (JK), and another researcher (DR) recorded field notes. Each group was audio recorded and later transcribed verbatim. Transcripts were de-identified and checked against the audio recording by one researcher to ensure accuracy of transcription and facilitate immersion in the data. At the conclusion of the fifth group, the authors agreed that theoretical saturation was reached (i.e. no new concepts were raised from discussions from previous focus groups).

6.4.1.2 Analysis

The transcripts were entered into NVivo 10 (QSR International, 2012) software to facilitate data analysis. Thematic analysis drawing on the principles of grounded theory was undertaken. Two researchers (JK, DR) independently reviewed the transcript line by line to inductively identify initial codes, and through discussion and a process of constant comparison within and across focus groups, developed preliminary themes. This ensured that the preliminary analysis captured the full breadth and depth of data. A third researcher reviewed the preliminary themes and supporting quotations. Relationships among themes were developed and illustrated using a thematic schema.

6.5 Results

Twenty-four participants (21 patients, 3 caregivers) participated in 5 focus groups (3 to 8 participants per group), which were conducted between November 2015 and March 2016. Participant characteristics are provided in Table 6-1. Three participants were kidney transplant recipients, however still met the GFR inclusion criterion for the study.

We identified five themes: exasperating stagnancy; supporting and sustaining change; fostering ownership; motivating and positive learning; and threats and ambiguities of risk. The themes are described in detail in the following section. Selected quotations that exemplify each theme are provided in Table 6-2. Figure 6-1 shows the conceptual links and relationship between the themes.

Table 6-1: Chronic Kidney Disease Participant characteristics (n=21)

Characteristics	**n (%)**
Gender	
Male	14 (66)
Female	9 (34)
Age (years)	66 (49-80)
41-50	2 (9.5)
51-60	2 (9.5)
61-70	12 (57)
71-80	3 (14)
Marital status	
Married/de-facto	14 (66.6)
Divorced/separated/never married	7 (33.3)
Employment	
Currently working	3 (15)
Retired	18 (85)
Stage of CKD	
3a	7 (33.3)
3b	7 (33.3)
4	5 (23.8)
5	2 (9.5)
Co-morbidities	
Diabetes	8 (40)
Hypertension	8 (40)
Cancer	5 (25)
CVD	5 (25)

Abbreviations CKD, chronic kidney disease; CVD, cardiovascular disease.

6.5.1 Exasperating stagnancy

6.5.1.1 Patronized by redundant advice

Participants believed that their priorities were misunderstood by the clinicians, including non-dietitians, who provided nutrition education. They felt patronized and given repetitive dietary advice from clinicians who would tell them the “same thing over and over and over”. They believed the advice was in-actionable and “very out of date”, and that they could more easily have “looked it up on the net” themselves. There was a preference for innovative dietary approaches which participants perceived to be more aligned with modern day research and that they had heard about in the media.

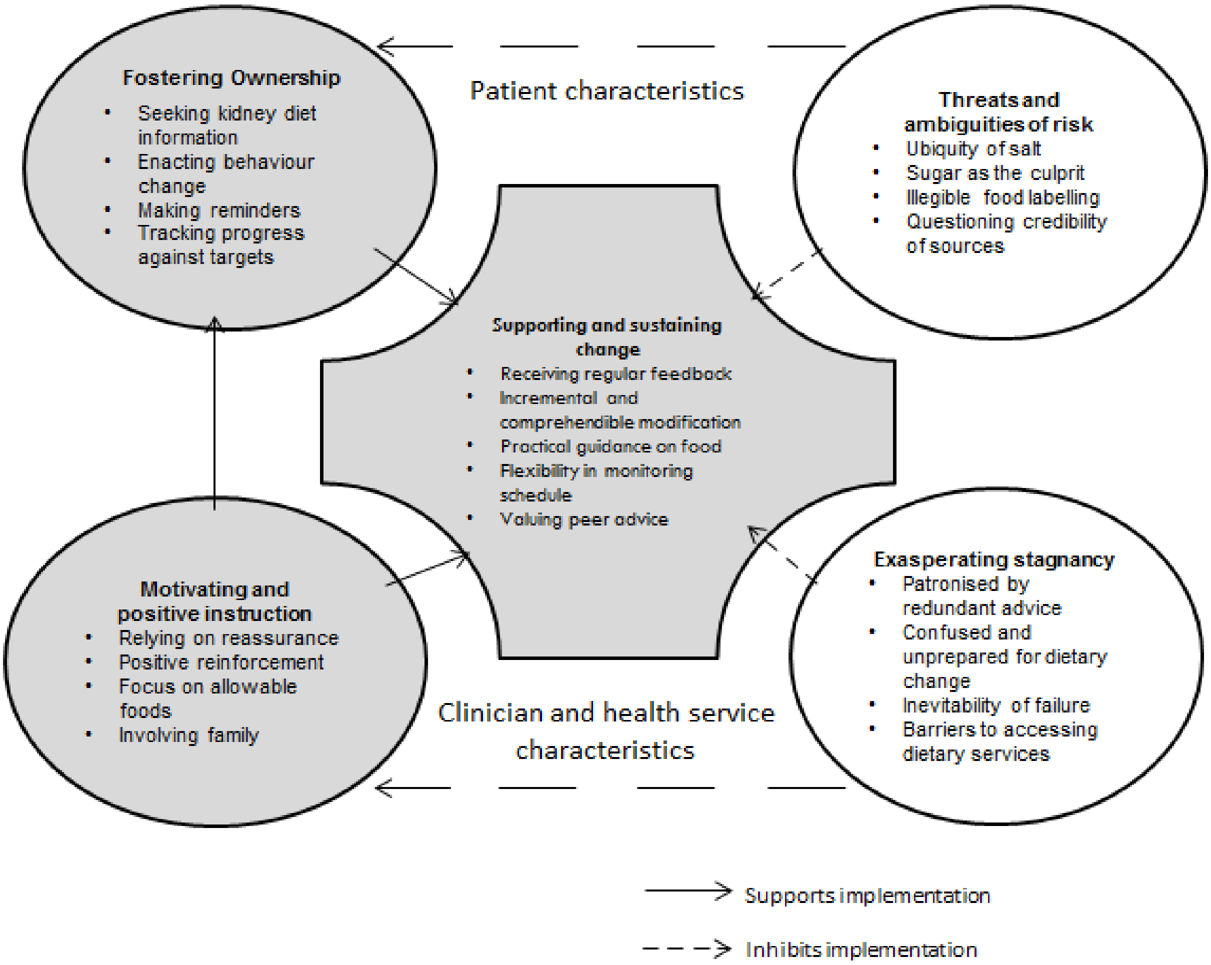

Figure 6-1: Thematic schema of patients' perspectives of dietary recommendations and telehealth. The dotted lines represent supporters and solid lines represent inhibitors pertaining to each theme. The top circles represent patient-centered characteristics, and the bottom circles clinician and health service characteristics.

6.5.1.2 Confused and unprepared for dietary change

Participants felt "disheartened" and confused by the lack of specific CKD dietary advice which lacked an individualized focus. They felt unprepared and given little-to-no support on how to implement changes: "I don't know what the heck I'm doing". They also expressed frustration that they had not been prepared for potential dietary changes when they first entered into the nephrology service, "instead of learning as you go" and before their kidney condition progressed.

6.5.1.3 Inevitability of failure

Participants described the predicament of multiple, and often conflicting, dietary recommendations for their co-morbidities. These conflicts were viewed as an impossible burden; "what in the world am I going to eat?" They expressed the view that they were being set-up to fail due to the in-cohesive approach. "[They tell you] don't do this for that complaint and this for that complaint", and they felt “what's left over I can either eat or drink is an ice cube.”

6.5.1.4 Barriers to accessing dietetic services

Participants mostly experienced healthcare consultations face-to-face. These appointments presented numerous barriers including taking time off work, cost of petrol, parking, and long waiting times. When participants were prompted on using telehealth for dietary education, they expressed that simple and familiar technology methods such as “a quick phone call or a quick text or something, or Skype” was low cost, easy and something they felt confident to use.

6.5.2 Supporting and sustaining change

6.5.2.1 Receiving regular feedback

Participants valued “regular contact” and “a bit of feedback” to track their progress as they saw it supporting their dietary change over time. They desired regular, more intense follow up in the early stages of modifying diet “just until you got your plan under way and under control” which could “spin out a bit more” (become less intensive) when their confidence increased. They highlighted the importance of the time between feedback being “individually tailored” to their condition and transitioning life circumstances.

6.5.2.2 Incremental and comprehendible modification

Participants stressed the need for dietary change to be taken “one footstep” at a time. They described their experience of instructional and overwhelming advice as like a “rubber-stamp on the forehead”. They suggested technology might play a complementary role to face to face contact through methods such as SMS and/or telephone follow up to highlight the “basic stuff [diet education] first” and then “further detail as you go along”.

6.5.2.3 Practical guidance on food

Many participants wanted a “list [or] guideline of what foods you could have… and what to leave out and maybe what to have occasionally”. Participants favored “the practical advice... you don’t hear that very often from anybody”. They wanted focused practical food-based advice to help them make sense of the nutrient focused information they were given previously.

6.5.2.4 Flexibility in monitoring schedule

Participants wanted the power to decide their own monitoring schedule. They wanted this to be two-way with “the option to ring the dietitian”. While they highly valued regular review, they believed increasing review appointments would add to their existing and competing problems accessing current healthcare. They were interested in how technology consultations could give them flexibility including the option to request that clinicians “ring you another day”.

6.5.2.5 Valuing peer advice

Many participants had never spoken about dietary challenges with other people with CKD. They thought the strategies and advice from peer support groups “sticks in your mind more, [and allows you to] cross-fertilize ideas”, but were unaware of group services available to them. Peer advice from dialysis patients was highly valued, and many described the prospect of dialysis as “scary”, something they wanted to avoid. They preferred to talk to their peers who were already on dialysis because they “knew what it was about” in a way that a clinician could not.

6.5.3 Motivating and positive learning instruction

6.5.3.1 Relying on reassurance

The potential nurturing role of the clinician was highly valued. They wanted to “feel reassured, [to] ask questions [and get a sense of] I’m okay”. Part of “feeling reassured [was knowing] that things can be done to improve [or] stabilize” their kidney problems. They felt they currently did not have an ongoing supportive partnership with their healthcare provider. They saw telehealth as one method to provide reassurance, to complement face-to-face, such as “a text saying ‘you're okay’, that’s terrific feedback”.

6.5.3.2 Positive reinforcement

Participants talked about both positive and negative experiences of clinicians giving them dietary advice. They preferred advice that was respectful, and “never… put you down” which they believed reinforced the changes they had to make. They avoided punitive and instructive approaches such as "you eat this", “you stick to this”. Clinicians that were “gentle” and “friendly” were viewed positively and they felt more comfortable, and happy to listen to dietary advice from them.

6.5.3.3 Focusing on allowable foods

Participants felt a CKD diet was very restrictive. They wanted information on "what foods you could have" rather than being told what nutrients to avoid. They described feeling "disheartened" by dietary restrictions which were viewed as "pretty severe". Because they didn't know what they were allowed to eat, they talked of using technology, such as the internet, however this wasn't always successful; "all they [internet sources] seem to list is high potassium foods" (and not the low potassium foods allowed).

6.5.3.4 Involving family

Participants felt that family and caregivers were gatekeepers to change. They discussed the importance of involving family members or friends, describing how they "regulate" their diets. They saw dietary advice as "a two-person-thing", which should include both "the cook and the patient". If family were not involved in dietary decisions or lacked understanding, they described having to prepare separate meals; "I can't feed anyone else the same stuff as I eat… you've got to take into consideration what they're going to eat".

6.5.4 Fostering ownership

6.5.4.1 Seeking kidney diet information

Participants described how they liked "picking up stuff off the internet", specifically for information not well explained by their clinician. Other participants sought answers through sources like "Google Scholar", "books", "newsletter" and "the news" in a quest to self-educate on dietary change. They felt that their doctors "don't have time" to answer all their questions, and favored "instant" and "non-invasive" methods to seek their information, such as the telephone and text messaging services.

6.5.4.2 Enacting behaviour change

When prompted to the types of dietary education commonly provided to patients with CKD, participants believed "a dietitian's got that stuff [dietary information] already out there". They argued that achieving dietary behaviour changes requires them as individuals to "want ownership of the problem", to "tell them [the dietitian] how I'm going myself" and drive their own change "if you want it, if you need it".

6.5.4.3 Making reminders

Participants discussed a desire "to get a sort of a reminder" as a tool to improve their own self-monitoring and efficacy. Participants discussed the importance of being reminded about their recommendations for dietary change, but also their clinic appointments. This included a reminder of dietary education delivered by phone or face-to-face; “how about a reminder about the call they were going to receive?”; or a text saying “I called you the other day, how are you going?”.

6.5.4.4 Tracking progress against targets

Participants preferred to “track” the results of their blood tests to “physically see” the progress made. They discussed that they often ask their doctor “what’s my readings?” for reassurance that they were “heading in the right direction”, and this was a motivator to make dietary adjustments. Participants suggested record keeping methods using technology so it was possible to track “the results of your last blood test” by using the internet and mobile apps such as “Carb Count [mobile app] or something like that”.

6.5.5 Threats and ambiguities of risk

6.5.5.1 Sugar as the culprit

All participants described sugar as “poison”, believing “white [sugar] is death” and it was a very important dietary belief to protect their kidneys from further damage. Many participants were of the opinion that ‘brown’ and ‘raw’ sugars were healthier choices and would use these in place of white sugar, whereas others “just stop sugar full stop”. Participants discussed many challenges to finding suitable “substitutes that is going to be interesting or tasty” in place of regular sugar.

6.5.5.2 Ubiquity of salt

Participants discussed that there “seem to be a lot of things on the market that have salt in them”. They described it as “pretty frustrating” and impossible to “find anything that hasn't got any salt in it”. While most participants were very “conscious of my salt”, some thought “it’s not good if you’re without salt… your body needs the salt”.

6.5.5.3 Illegible food labelling

Many participants recognized label reading as important to make better food choices. They faced the dilemma of identifying a low sugar product, only to find it was high in salt. They believed food “labels should be changed” particularly regarding their size and format to “be a decent legible size”. Many participants required glasses to read labels, and were frustrated about taking “twice as long to do the grocery shopping”.

6.5.5.4 Avoiding processed foods

Participants reported a common belief that the food supply was dominated by processed foods. They reported having "trouble" with avoiding "all the processed stuff, which is really difficult to do without these days". They discussed what would "be the best [would be] if some of the processed food had less salt [and weren't] full of preservatives" which they described made it "so hard" to rationalize what to prioritize.

6.5.5.5 Questioning credibility of sources

Participants were seeing many different healthcare professionals, and regularly received new and sometimes conflicting advice. Those who frequently sought out information themselves described the need to "check with somebody that knows what they're talking about" to question the reliability of information they found, particularly if it was food related and something they had not been previously advised about. They discussed how they would "research something [on the internet] and know that I could be possibly getting the wrong information [so they would] print it out and run it by the doctor".

Table 6-2: Selected quotes for each sub-theme within the five key themes developed

Theme	Quotation
Exasperating stagnancy	
Patronised by redundant advice	Last time I got a piece of paper that said this this this and I really come away with very little information." So I just thought no, I would like to have somebody with newer ideas. (Woman, FG4) Well, they tell me the same thing over and over and over and they - as you said earlier, I know I'm not to eat cake. I know I'm not to have this and that. (Man, FG2)
Confused and unprepared for dietary change	Well, they got me early, reasonably early I guess. And, yes, it would have helped to have a bit of learning about it all. We learnt as we went along. So yeah, if I was able to learn a bit more about it then instead of learning as you go, that would've been good. (Woman, FG4) In the past [earlier stage of CKD] it would have been interesting I guess, but I don't know. A few – Is diet is gonna bring, diet isn't going to bring creatinine down, is it? (Man, FG3)
Inevitability of failure	There's probably other [diet changes] things that I should have given up too, but I can't remember them all. I used to love my seafood but I also suffer from gout so all I have to do is add up the things for the kidney, the heart, the diabetes and the gout and what's left over I can either eat or drink it as an ice cube. (Man, FG1) I mean, this diet business is always "You don't do this for that complaint and this for that complaint" and - - it's very confusing. (Woman, FG1)
Barriers to accessing dietetic services	Yeah, but also, it would be annoying for you to come and see a dietitian every three weeks or four weeks because you got to take time off work, you know? Yeah, you gotta get in the car, drive down there, park, blah, blah, blah, blah. You know, you wouldn't do it. You'd just find an excuse not to do that all the time. But, yeah, a quick phone call or a quick text or something, or Skype or whatever, yeah, would be easy. (Woman, FG5)

Supporting and sustaining change	
Receiving regular feedback	When you first start she's ringing up all the time, could be weekly, and that was seeing how you're going and then as you're getting better it gets - as usual, you know, it spins out a bit more. (Woman, FG1) "A way of… getting in touch every six weeks and asking your readings and all that sort of thing, I mean, that's terrific feedback". (Man, FG1)
Incremental and comprehendible modification	I reckon, the basic stuff first of all. What they've really gotta work on. And then we come later on to these things, it would be nice if you didn't eat these things, label reading and so on and so forth. But I think the first plunge is sort of what's important, cut out salt, maybe less of the potassium and so on. And then I think you get into further detail as you go along. But I think there's a few basic things they need to know the first meeting. (Man, FG4)
Practical guidance on food	I would suggest that, you know, if you were advising someone on cutting back salt, I would also try to advise them on their overall dietary guidelines, you know, like, the old pie chart, two thirds of your meal is fruit and vegetables and, you know, one third is protein and stuff like that. And concentrate on foods that don't have the high salt content so don't fill yourself up with cereal first thing in the morning or have a sausage roll at lunch time. Go for a go for a salad sandwich say. (Man, FG3)
Flexibility in monitoring schedule	It would definitely be better than coming into the hospital every single review, especially if it's just a simple, "How are you going? How are you coping?" (Man, FG3) That sort of thing because sometimes if you - if you ring they mightn't be feeling well and you just cannot be bothered. But if they give you the opportunity of saying "Can I call you another day?" "Yes, please do." You know, but just that particular day, you know what it's like when you have your off days. (Woman, FG4)
Valuing peer advice	Yeah. I've seen [group based education] – it's quite relevant 'cause it's very – you pick up more than a one to one with a group. Definitely, it's experience of different things. It sticks in your mind more anyhow, put that way and – yeah. (Man, FG5) [My HCP] who works there who's a lovely guy, he's as slim as anything, and openly talks about his diabetes and you sort of feel "Ah, he's the same as me, I feel good." (Woman, FG3)
Motivating and positive learning instruction	
Relying on reassurance	I can ask questions, because the important thing is to leave your doctor, your specialist, to feel reassured. Now, I say now, "Look, my potassium level, my this level –"he said, "Look, for your person and your age, considering you have that and that, it's fine. Because it's been very stable for three years." "Okay. Thank you doctor, I feel reassured." So, let's not panic about my kidney anymore, other than what aggravates it, the diet and this and that now. So I'm doing a bit better, but it's all back to communication, reassurance. (Man, FG5) Only just reassurance. Reassurance that things can be done to improve things. (Woman, FG5) Yes. I think reassurance is very important. (Man, FG4)
Positive reinforcement	And recognition. If you - like, it sounds silly but if you lose a kilo in a month and the dietitian says to you "Oh, wow, you've lost a kilo, that is fantastic, what do you put it down to? What was the main cause for you losing that?" Make the person think about what they've done to lose that. (Man, FG2) And they don't tell you off. You know how you don't want to go because you think "Oh, God" but they never do put you down which is a big benefit, yeah, because if they did I wouldn't go. (Woman, FG1)
Focussing on allowable foods	Well, it gives them options. Saying, "Cut the salt out," is pretty severe, like cut your nose off to spite your face, you know? Instead of eating so much with all

	the all the salt in it, why not cut that out and substitute it with something else and give them something to substitute that is going to be interesting or tasty. Let's say that everything that's bad for you tastes good. Let's go there. If it tastes good, it's bad for you. (Man, FG3)
Involving family	You've got to involve the partners, because there's two people involved. (Woman, FG2) But the other suggestion, I have, which has worked for me – is take a partner with you when you go to see a dietitian. Because the partner can often remember things that you don't hear properly. (Man, FG4)
Fostering ownership	
Seeking kidney diet information	So I think – when I was researching about high potassium and they said, "High fibre white bread is better for me than wholemeal or multigrain," or any of those. So I switched to high fibre white bread now rather than rye or multigrain or something. (Man, FG3) Use a lot of herbs and spices. Of course, I pick up stuff off the Internet, 'cause I often have a look at articles that come through. My nutritionist very often sends me stuff and says, "Read this". (Man, FG4)
Enacting behaviour change	I'd find out what is the motivation behind the person. What is the person's motivation?... You need to find that out… Get to the motivation for whatever that wants to keep them going, then educate them on how to do it, and then give them the tools to do it, but make it their responsibility. I think you have to have ownership. (Woman, FG4)
Making reminders	I've got in my handbag always how much salt I'm allowed to have on a little piece of paper… 10 grams of fat per 100 grams. 3 grams of saturated fat per hundred grams, 15 grams of refined sugar per hundred grams, 120 grams of sodium chloride and three grams of fibre per serve. (Woman, FG2) It would be good for me to get a sort of a reminder about, you know, fat or sugar and I could say to my husband "Look, I just got a reminder, remove all fat from meat" blah blah blah. (Woman, FG2)
Tracking progress against targets	I have them [blood tests] done quarterly and he does each quarter and he – whenever he gives me one, it's got four quarters on it. So, I can at least track how I'm doing at the time. (Man, FG4) And I can physically see it. It was only small per day but over a month and - and that sort of registered pretty quick and I sort of analysed that and I could see that I was heading in the right direction. (Man, FG2)
Threats and ambiguities of risk	
Sugar as the culprit	I remember reading somewhere or hearing somewhere that anything white is death. Like white rice is bad for you, white bread is bad for you. Anything that's white is worse for you than say whole grain. Yeah, so, avoid white bread and go for whole grain. That's a healthier alternative. Salt is gonna kill you. White rice is not good for you, but brown rice is better for you and things like that. (Man, FG3)
Ubiquity of salt	Trying to find salt - salt-free - I'd love a salt-free soy sauce or a low-salt soy sauce. There just seem to be a lot of things on the market that have salt in them. And that's my bugbear, is trying to find something that doesn't have - well, I can't find anything that hasn't got any salt in it. You know, even you go to buy - get a salad, get a salad at a restaurant, that's without - with cheese and all that sort of stuff, and you can't have cheese because it's got too much salt in it, dah, dah, dah, dah, dah. (Man, FG1)
Illegible food labelling	No, for many things, like, yeah, the labels have a lot of information and I think the labels should be changed slightly too in different areas for sure. For example, that shouldn't be so small, they should be a decent legible size, like, nearly, probably, as twice the size of the advertising material, 'cause if they're a good company, they'd be proud of what they've got. (Man, FG4)

	Yeah, I - I think the dietitians actually educating us to read the back of the packets [is important]. (Woman, FG2)
Avoiding processed foods	It's pretty frustrating. I think. Yes. I just think I buy lentil burgers and I think they'd be good for me, but they blow me up too and I think there's a lot of sugar, salt and herbs or whatever in them. (Woman, FG3)
Questioning credibility of sources	I'm somewhat sceptical on some of the stuff. So, I then tend to check it with somebody that knows what they're talking about because there's lots of claims made on the Internet about various things. A lot of them are not researched properly. (Man, FG4) Usually the government websites are okay, usually. But once you go outside of that, it's like, no, just forget it. (Man, FG4)

6.6 Discussion

This qualitative study explored the experiences of CKD participants in relation to dietary management, and their perspectives on the potential for telehealth to support dietary change. Participants in our study described feeling misunderstood by clinicians providing dietary advice, and felt confused with conflicting guidance from different clinicians. In addition, they highlighted many barriers to seeing clinicians in face-to-face settings, which did not meet their preference for regular review and feedback. Participants desired practical guidance on foods and a flexible monitoring schedule to support and sustain dietary change. They preferred clinicians who provided reassurance, were positive, involved their family and/or caregivers, and focused on foods that were allowed in the diet, as opposed to imposing food restrictions. To gain control of their diets, they felt responsible for seeking out additional dietary information, enacting dietary changes and self-tracking their progress over time. This was an exceptional challenge for participants whose health care delivery experience was not conducive to making dietary behaviour change.

This is the first qualitative study to describe the CKD patient experience with dietary advice provided in nephrology services. Although we know that patients struggle with adhering to their diet and fluid recommendations, and desire more flexibility and individualised support,[3] our study has focused on the source of these recommendations as well as their delivery setting. For the first time, we show that diet recommendations come from a myriad of sources (and rarely from qualified dietitians). People with CKD find this a disorienting and confusing experience. Our study suggests that telehealth may be viable options to overcome these patient-centered care barriers. Importantly, patients did not show preference for what telehealth options would be 'the best', as long as these were cheap, easy to use, and gave them flexibility. We believe this will help future intervention development and continued efforts to improve patient-centered care in nephrology services.

Participants felt their priorities for dietary change were neglected by the wider healthcare community (including primary care and nephrology services). They described an inflexible, outdated, and patronizing consumer experience, not aligned to patient-centered care. Such shortcomings in delivering patient-centered care in nephrology services has been reported previously[18,19] and is increasingly recognized as a barrier to delivering effective clinical care, to improve patient-clinician communication and overall health outcomes.[20]

The findings of this study highlight that people with CKD want advice and greater emphasis on prevention and progression of CKD in the early stages. Therefore, a coordinated model of care fostering ownership over their dietary self-management and supporting change long-term is needed. General practitioners and nephrologists are best placed to initially highlight the importance of diet to newly diagnosed patients, and to refer to a dietitian shortly after diagnosis. A coordinated and multidisciplinary approach to patient care has been shown to improve patient outcomes,[21] is a strong service need and reflects patient's desires. There is evidence to support healthy dietary change in CKD, including the reduction of dietary sodium for lowering blood pressure and proteinuria,[4] and protein modification for protecting residual kidney function.[22] Furthermore, the adoption of a healthy dietary pattern may reduce incident CKD in the general population[23] and mortality in established kidney disease.[24] Yet despite an evidence-base for prevention, this patient population feel unable to access dietary services, at a time they are motivated to prevent their disease progression.

The current healthcare workforce and models of care appear unable to meet patient expectations of patient-centered care. With current service delivery unable to adjust to increasing consumer demand,[25] many patients will never see a renal dietitian. Instead, patients may only receive these services if they reach ESKD, where they may be referred to manage acute concerns, such as hyperkalemia. However, ESKD is the patient-centered endpoint they describe being desperate to avoid. While services continue to neglect this prevention focus, patients perceive stagnancy in healthcare delivery, are innately confused, and feel unprepared to make dietary change. This can impede patients' self-efficacy for integrating dietary self-management, leaving them to seek diet information online which often lacks evidence and may cause harm.[26] If current service models cannot address people's self-efficacy in the early stages of CKD, this may lead to faster progression to ESKD.[27]

Using telehealth shows considerable promise for improving self-efficacy in people with CKD, and may overcome current healthcare limitations and improve patient-centered care. Our group of CKD participants expressed interest in telehealth methods that would complement their traditional care rather than replace it, providing the delivery modality was relevant and familiar to their skills and level of health literacy. Participants preference for telehealth primarily centered on overcoming the incoherent dietary advice in current health service delivery. Many participants were already using mobile devices and the internet, particularly for seeking information outside of their usual care, therefore these modalities were often preferred and acceptable to support self-mangement.[28] These methods were seen as ways '*Receive regular feedback'*, *having 'Flexibility in the monitoring schedule',* able to '*Involve family',* and overall '*Foster ownership'*; while overcoming the growing *'Barriers to accessing dietetic services'.* Using telehealth has been shown to facilitate dietary change[12] and could overcome the common healthcare barriers experienced in face-to-face settings, including demographic isolation, working hours, and forgetting appointments.[29] Additionally, telehealth methods could decrease commonly reported healthcare access barriers, specifically administrative errors, access to clinic facilities, parking and unfavorable opening hours of clinics in face-to-face settings.[19,30]

It is important to note that telehealth may introduce the opportunity for health services to utilize non-dietary trained personnel in its delivery. However, the results of this study indicate that the majority of participants had never seen a renal dietitian, leading to many of their dietary challenges, and the health service perceived as stagnant and unsupportive. Based on these findings, we recommend any telehealth dietary intervention should involve a dietitian, at least in the development of materials (text messages; call scripts; resources) and preferably in the subsequent delivery of the intervention content. Given telehealth's novelty in CKD, any program should be pre-tested with the patient demographic and ideally trialed for feasibility and cost-effectiveness prior to implementation.

As far as we are aware, this is the first study to describe the experiences of people's dietary management in pre-dialysis CKD and perspectives on the potential to use telehealth to support dietary change. The use of a semi-structured questioning approach, to encourage participants to discuss their feelings and attitudes (both positive and negative) was a strength which somewhat mitigates the inherent researcher bias. However, this study is not without limitations. Given its qualitative design, the generalizability of themes to other populations with CKD is uncertain. Although we attempted to achieve a demographic reflective of current prevalence in Australia, we did not recruit participants of Indigenous heritage, or those living outside metropolitan areas. However, the results are generally consistent with similar ESKD qualitative studies.[3] Future research should specifically target these populations, who are known to have higher burden of CKD and who may experience different barriers to dietary change and technology use.

In summary, people with pre-dialysis CKD desire a preventative approach to CKD progression however, are stymied by restriction-focused dietary advice and a lack of dietetic service provision in early stage CKD. Clinicians need to be positive and motivating, and consider the individual’s goals for dietary change, to empower patients to better cope with dietary recommendations, which could help improve patient-centered outcomes. Telehealth methods such as the telephone and text messaging were viewed acceptable over other telehealth options (and to complement face to face care) to facilitate dietary follow up. These modalities appear to meet the patients’ expectations of service delivery, and may assist in dietary change.

6.6.1 Practical application

Patients with CKD experience a range of barriers to enacting dietary behaviour change. These partly stem from the characteristics of health professionals and barriers to traditional healthcare delivery. Clinicians should align with a patient’s priority for dietary change, and avoid patronizing advice focused on nutrient restrictions. This patient-engagement study can be used to develop patient-centered telehealth programs, and guide its implementation in a CKD service. To use telehealth to support dietary change, clinicians should consider text messages and phone calls, as they are viewed to facilitate regular, repeated interaction and giving patients the support they require for long-term dietary change.

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Chapter 7 - The Evaluation of Individualized Telehealth Intensive Coaching to Promote Healthy Eating and Lifestyle in Chronic Kidney Disease (ENTICE-CKD): A Mixed Methods Process Evaluation

7.1 Preface

In the previous chapter (Chapter 6), people with CKD shared their experiences with dietary challenges and the potential of a telehealth program to overcome these dietary challenges. From this study, it was clear that clinicians needed to deliver up-to-date nutritional advice but keep it relevant to the patient's diet priorities. Participants wanted flexible services that could offer continued support and monitoring, until they were feeling confident in self-managing themselves. Chapter 6 introduced the concept of using telehealth and showed that people with CKD were open to using these methods, providing they could meet these needs, were tailored to their condition, and delivered using familiar technologies.

The findings from Chapter 6, as well as the evidence synthesis in Chapters 3, 4, and 5 were used to inform the development of a patient-centred telehealth-delivered dietary intervention in the stage 3-4 CKD population. The telephone and mobile phone were identified as the best delivery methods, as participants in the qualitative study were most comfortable using these telehealth modalities. The delivery schedule was decided to be fortnightly with weekly text messages to ensure contact and feedback was regular, and the diet advice was not restriction focused, but was comprehensive and delivered in steps across each phone call.

Chapter 7 details the first randomised controlled trial of a telehealth-delivered dietary intervention in CKD. This chapter describes a pilot study testing the feasibility and acceptability of the telehealth-delivered intervention which was developed following the work reported in Chapters 3, 4, 5, and 6. This chapter addresses the absence of quality evidence regarding the feasibility and acceptability of this intervention strategy, as well as provides insight into the preferred delivery mode for text and telephone-based counselling. As a pilot study, it is intended to provide critical evidence for future large-scale dietary intervention studies.

7.1.1 Publication status

The manuscript presented in this chapter is currently under review by the peer-reviewed journal the *Journal of the Academy of Nutrition and Dietetics*. The manuscript presented in this chapter is formatted to a consistent thesis style. However, the grammar, headings, and references (in-text and bibliography) are unaltered in accordance with the journal publishing guidelines.

Citation: **Kelly JT**, Warner MM, Reidlinger DP, Hoffmann TC, Craig J, Tong A, Reeves M, Johnson DW, Palmer SC, Campbell KL. The evaluation of individualized telehealth intensive coaching to promote healthy eating and lifestyle in chronic kidney disease (ENTICE-CKD): A mixed methods process evaluation. [*Under Review*]

7.1.2 Related work to this Chapter completed by the candidate

One other manuscript relating to this chapter is currently in draft, which the candidate is a co-author. This work is the qualitative follow-up relating to the experiences of participants who completed the trial this proceeding chapter discusses. While this paper is not a primary publication within this thesis, the candidate was directly involved in the study design and recruitment of participants and supervised the student researcher during this project. The findings complement the overarching aim of this thesis, and is available in Appendix B.

- Warner MM, **Kelly JT**, Reidlinger DP, Tong A, Campbell KL. Patient acceptability and experiences of a telehealth coaching program to improve diet quality in CKD: A semi-structured interview study. [Draft manuscript to be submitted]. *See Appendix B*

7.2 Research snapshot

7.2.1 Research question

What is the feasibility and acceptability of a personalized telehealth intervention to increase diet quality in adults with stage 3-4 chronic kidney disease (CKD)?

7.2.2 Key Findings

In this pilot randomized controlled trial involving 80 participants with stage 3-4 CKD, a personalized telehealth intervention was found to be feasible and acceptable. Ninety-six percent of telephone calls were successfully completed, and retention was 95% after six months. All (100%) participants in the tailored intervention viewed the text messages as useful in supporting their dietary change, compared to 69% of participants in the non-tailored text message (control) group ($p<0.01$).

7.3 Abstract

7.3.1 Background

Telehealth interventions have the potential to support dietary management in people with chronic kidney disease (CKD).

7.3.2 Objective

To evaluate the feasibility and acceptability of a personalized telehealth intervention to increase diet quality in adults with stage 3-4 CKD.

7.3.3 Design

Mixed-methods process evaluation of a randomized controlled trial (RCT).

7.3.4 Participants/setting

People with stage 3-4 CKD were recruited to an RCT from three hospitals in Australia.

7.3.5 Intervention

The intervention group received one telephone call per fortnight and 2-8 tailored text messages for three months, and then 4-12 tailored text messages for three months without telephone calls. The control group received usual care for three months then non-tailored education-only text messages for three months.

7.3.6 Main outcome measures

Feasibility (recruitment, non-participation and retention rates, intervention fidelity, and participant adherence) and acceptability (questionnaire and semi-structured interviews).

7.3.7 Statistical analyses performed

Descriptive statistics and qualitative content analysis.

7.3.8 Results

Overall, 80/228 (35%) eligible patients who were approached consented to participate (mean age 61.5±12.6 years). Retention was 93% and 98% in the intervention and control groups, respectively, and 96% of all planned intervention calls were completed. All participants in the intervention arm identified the tailored text messages as useful in supporting dietary change. In the control group, 27 participants (69%) reported the non-tailored text messages were useful in supporting change. Participants in the intervention group reported that the telehealth program delivery methods were practical and able to be integrated into their lifestyle. Participants viewed the intervention as an acceptable, personalized alternative to face-face clinic consultations, and were satisfied with the frequency of contact.

7.3.9 Conclusions

The ENTICE dietary coaching program is a feasible and acceptable intervention for supporting dietary change in stage 3-4 CKD. A larger-scale randomized controlled trial is needed to evaluate the efficacy of the coaching program on clinical and patient-reported outcomes.

7.4 Background

Chronic kidney disease (CKD) is a progressive condition affecting over 10% of the population worldwide.[1] Diet is a modifiable risk factor for the progression of CKD to end-stage kidney disease (ESKD).[2,3] Typical dietary advice includes restricting individual nutrients, such as sodium, protein, potassium and phosphate. However, there is little evidence regarding the adherence to, and efficacy of, nutrient-specific dietary advice.[4] Recent evidence shows that following a healthy dietary pattern, as a whole food-based dietary pattern is associated with a reduced risk of death in established CKD.[5] A focus on foods rather than single nutrients may also facilitate increased adherence to dietary change in CKD[5,6] which is otherwise a challenging due to dietary complexity and competing demands of self-management.[7] Overcoming these barriers to implementation of sustained dietary change are necessary to test whether improving diet quality alters patient-centered outcomes.

Providing regular and individualized dietary support required for those with CKD comes with geographical, time and financial barriers.[8] To test whether increasing diet quality (through dietary pattern) may attenuate the progression of CKD and elevated cardiovascular risk on a sufficient scale for a randomized controlled trial (RCT), alternative modalities that are effective in supporting dietary management are needed. Telehealth modalities, particularly telephone-based and text message coaching, present an opportunity to overcome barriers and challenges that people with CKD encounter in accessing health care services.[7,9] Telehealth interventions may facilitate an increased frequency and quality of contact between the patient and healthcare professional,[10,11] which may improve acceptability, uptake and adherence to interventions[12] and better align with a patient-centered model of care.[9] Compared to face-to-face consultations,[11] telehealth modalities are effective in reducing chronic disease risk, including improving diet quality, fruit and vegetable consumption and reducing dietary sodium intake.[10] Text messaging has been utilized to ‘extend contact’ after an intervention and has been shown to maintain clinical outcomes and minimize intervention decay.[13,14] A systematic review of text message health interventions highlighted the need for better evidence on the relative effectiveness of text-based interventions including message delivery (incorporating frequency and timing), level of interaction (i.e. response and feedback) and impact of additional interventions (such as a combination with telephone, face-to-face, video or internet).[15]

While dietary patterns aligned with a higher diet quality are associated with improved lower mortality in CKD, the level of coaching required to achieve and support this dietary change is largely unknown. Furthermore, evidence to support the level of tailoring, and the delivery method that is most feasible and acceptable for patients with CKD, is lacking. Therefore, this pilot study aimed to evaluate the feasibility and acceptability of telehealth-delivered dietary coaching to support the improvement of dietary quality in stage 3-4 CKD.

7.5 Materials and methods

We used a mixed methods design, whereby qualitative data on the patient experience were embedded within quantitative data relating to participants recruited into the Evaluation of iNdividualized Telehealth Intensive Coaching to promote healthy Eating and lifestyle in Chronic Kidney Disease (ENTICE-CKD) program. All data was prospectively collected. This pilot randomized controlled trial was prospectively registered (ACTRN12616001212448) and reported based on the CONSORT checklist.[16] This trial was approved by the Metro South Health Service District Human Research Ethics Committee (EC00167) and Bond University Human Research Ethics Committee (EC00357). All participants provided written informed consent.

7.5.1 Design

This multi-center, randomized controlled trial was conducted from November 2016 to November 2017. The dietary intervention was designed using the social cognitive theory,[17] with a patient-centered focus on improving self-management to reduce dietary sodium intake (<2300mg/day) and increase dietary quality in accordance with the Australian Dietary Guidelines (see Table 7-1 for intervention guidance).[18] Interventions were adjunct to usual nephrology care from treating physician(s) and renal team members, including ad hoc referrals to allied health practitioners during the study.

7.5.2 Participants

Participants were recruited from three tertiary nephrology units in Queensland, Australia over a 6-month period (November 2016 until May 2017). Inclusion criteria were: adults over 18 years of age; stage 3-4 CKD (eGFR 15-60mL/min/1.73m^2); and access to a mobile device capable of receiving text messages and telephone calls. Exclusion criteria were: anticipated dialysis commencement or kidney transplant within the following 12 months; pregnancy; non-English speaking; cognitively impaired; or deemed unfit to participate by their treating nephrologist.

Eligible participants were randomized on a 1:1 ratio into one of two groups (stratified by recruiting site and diabetes status). Randomization was completed by computer-generated random numbers carried out by an independent statistician not involved in the study.

7.5.3 Study treatment

The ENTICE-CKD program was completed in two three-month phases in both the intervention and control arm of the study as detailed in Figure 7-1. The intervention group received fortnightly telephone calls for three months (phase 1) and tailored text messages for six months (phase 1 and 2). The control group received usual care for three months (phase 1), followed by non-tailored education-only text messages for three months (in phase 2). Each participant was involved in the trial for six consecutive months. All participants were provided with an ENTICE-CKD workbook at the baseline visit (Appendix J). The 90-page workbook included information on setting *specific, measurable, achievable, realistic, and time-bound* (SMART) goals; eating well for kidneys (based on the Australian Dietary Guidelines);[18] active living (based on the Australian Physical Activity Guidelines);[19] role of diet in kidney disease, strategies for planning, self-monitoring checklists, and a list of useful websites, apps, and recipes for further reference.

Screening and recruitment

↓

Randomization

↙ ↘

	Week	**Intervention group**	**Control group**
Phase 1	1	Baseline Visit	
	2	6x fortnightly telephone	Usual Care
	4	calls + tailored text	(workbook only)
	6	messages	
	8	+ workbook	
	10		
	12	Mid-point visit + telephone call	
Phase 2	14	Tailored text messages	Educational text
	16		messages
	18	Telephone call	
	20	Tailored text messages	
	22		
	24	End-point visit	

Figure 7-1: Summary of ENTICE-CKD program delivery.

7.5.3.1 Telehealth coaches

Each participant was assigned to a telehealth coach at baseline. The participant had the same coach for the duration of the program. The telehealth coaches were registered dietitians (Australian equivalent) with additional training in renal nutrition, behavior change, and motivational interviewing; were external to the recruiting sites and had never met the participants; and were not involved in any outcome data collection.

Table 7-1: Dietary targets adopted in the ENTICE-CKD intervention workbook, telephone calls and text messages.

Food group	**Dietary target** (serves/day)	**Considerations**
Grains/cereals	3-6 (>50% whole grain)	Replacing refined carbohydrates for wholegrains
Vegetables and fruit	5-7	Low potassium alternatives as appropriate
Low fat dairy	2	250mL milk, 40g cheese, 200g yoghurt
Lean meat, poultry and fish	<2 (130-200g)	Modified for protein (aiming for 1.0 g/kg/day)
Fats and oils	20 to 40g	Emphasise healthy oils
Dietary sodium	<100mmol/day (6g salt)	Replace takeaway and processed foods for
Added sugars	<10% total calorie intake	fresh food and healthy cooking methods
Discretionary choices	<2	Limit where possible

Abbreviations – g: grams, kg: kilogram, mL: millilitre.

7.5.3.2 Phase 1

The participants in the intervention group received six fortnightly telephone calls in phase 1 which were scheduled on weekdays at a time of the participants choosing (from 7am to 7pm). The first call was scheduled for 45 minutes and five subsequent for approximately 30 minutes. Each call was based on established protocols and call scripts. The telephone call content was guided by the workbook topics, structured according to the 5A's framework (Assess, Advise, Agree, Assist, Arrange),[20] and individually tailored to participants using relevant educational strategies, and in consideration of the participant goals and co-morbidities. Where required, 24-hour dietary recalls were undertaken during coaching calls to track adherence and progress with goals. Coaches used Microsoft Excel[21] to document progress of each call and log information including goal setting, implementation intentions, self-monitoring tools, call attempts and durations, and text message preferences.

In addition, participants in the intervention group received from two to eight text messages scheduled between coaching calls with the actual number and time of day determined by each participant's preference. Text categories included: educational; self-monitoring; and goal setting. The schedule of text messages for the intervention and control group in phase 1 and 2 is detailed in Table 2. The text messages were sent using a web-based, semi-automated text message management platform (Propelo, www.propelo.com.au), developed and administered by The University of Queensland's School of Public Health.[22] The investigators, in collaboration with local nephrologists, dietitians and evidence-based practice guidelines, designed the library of text messages, which were then reviewed for comprehension by a group of patients, nephrologists and members of the investigator team. The text message library was imported into the software platform, which was designed to tailor text messages based on: participant's name; individual goals; barriers to achieving goals; and, participant-identified solutions to overcoming those barriers. These tailoring variables were modified as required following each coaching call.

As shown in Table 2, participants in the intervention group could receive one 'goal check' (per goal) per fortnight in phase 1 and up to 2 goal checks (per goal) per fortnight in phase 2. These goal checks required the participant to respond to the text with a "yes" or "no" which prompted the software to send a pre-determined response. An incoming text reply outside protocol (i.e. not a "yes" or "no" response) was classified as an 'unrecognized response'. This triggered an email to the participant's coach and was only responded to where participants expressed considerable risk to their health (e.g. symptoms needing medical attention).

Participants in the control group received no coaching or text messages between the baseline visit and three months (phase 1). The control group continued to receive standard care under their treating nephrologist and were encouraged to work through the ENTICE-CKD workbook at their own pace.

7.5.3.3 Phase 2

At three months, participants in the intervention group completed a tailoring telephone call to determine individual preferences for the timing and frequency of text messages for phase 2. At 18 weeks (i.e. half way through phase 2), participants received a second tailoring call where they could modify the timing and frequency of text messages and could update their goals. Intervention group participants chose text message frequencies for the same types of texts that they received in phase 1 (educational tips, self-monitoring, goal checks).

Participants in the control group received non-tailored education-only text messages (described in Table 7-2).

Table 7-2: Text messaging framework and related social cognitive theory constructs in the 24-week ENTICE-CKD trail.

Text message type	**SCT construct**	**Example text**	Intervention group		Control group	
			Phase 1	Phase 2	Phase 1	Phase 2
Educational	Outcome expectations (providing information on consequence)	Dietary fibre intake reduces ur cholesterol levels and controls ur blood sugar. Include wholegrain breads & cereals, fruits & veg regularly	2-6	1-4	NA[a]	6-8
Self-monitoring	Self-regulation Assist with perceived impediments and facilitators of behavior	Hi [name], are you keeping track of ur fruit/vegetable intake every day? Remember ur goal to meet at least 5 serves this week	0-2	1-4	NA	NA
Goal check of behavioral goals	Self-regulation	Hi [name], did you reach ur goal to eat 5 fruits/vegetables 4 times this week? Text me back yes or no to let me know	2	2-4	NA	NA
Educational Permutations (Safety protocol)	Low potassium diet	Choose high fibre, low potassium breakfast cereals. Good choices are Multigrain Weetbix, Rolled Oats, Guardian, Oatbritz, Special K	0-2[b]	0-2[b]	NA	0-2[b]

[a] NA = not applicable
[b] Educational permutations were only available for coaches to use if a participant experienced hyperkalaemia or hyperphosphataemia

7.5.4 Data collection

Each participant attended a baseline, three-month mid-point, and six-month end-point visit with a local site investigator (nurse or dietitian blinded to group assignments) at their study site to collect all clinical objective data (not reported here). All participants' study visits were scheduled on separate days or hours apart to avoid risk of contamination bias. Basic demographic data (including participant's age and gender) were recorded at baseline. Socio-economic status was estimated from participants' postcodes, according to the Index of Relative Socio-economic Advantage and Disadvantage (IRSAD).[23] Baseline health literacy was collected using the single item Literacy Screener which classifies Health Literacy as good or limited based on the single question, "How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?".[24]

7.5.5 Reach and retention

Recruitment and non-participation rates were captured across the three recruitment sites, with a goal to achieve the target sample size of 80 participants in the six month recruitment time frame. Retention rate was measured at three and six months in both study groups, with successful retention defined as 80% at the six-month study end.

7.5.6 Intervention delivery

Individual cases were discussed fortnightly between the coaches and the lead investigator to support consistent intervention delivery. All coaching calls were audio recorded, from which 10% were assessed for consistency by peer-review by an individual external to the project. The following fidelity data were collected and stored in a Microsoft Excel[21] database throughout the trial: number, duration and content of coaching telephone calls; number and type of text messages delivered; number and type of text message responses; and time spent by coaches for each interaction.

7.5.7 Intervention adherence

Adherence was defined as successfully completing five of the six telephone calls for the intervention group. We also collected data on individual participant adherence to the prescribed dietary intervention, collected by coaches in each telephone call using a call log template in Microsoft Excel.[21] In the call logs, coaches described evidence of the participant's overall progress, evidence of self-monitoring, goals set and implementation intentions (behaviours implemented to achieve goals) during each call, which was quantified in counts to capture participant adherence.

7.5.8 Acceptability

A utility and acceptability survey of the text message component of the ENTICE-CKD trial was collected from all participants at the six-month end of study visit (Appendix K). The survey included 13 items, developed specifically for the study, with five items asking participants to rate on a 5-point Likert scale from 1 'strongly disagree' to 5 'strongly agree', four items asking participants yes/no questions, and four multiple choice questions, based on previous methodology in cardiac patients.[25] In addition to this, during the sixth telephone call (three-month study mid-point; for intervention participants only), coaches obtained verbal consent of participants to be approached to complete an interview relating to their experiences of the intervention.

Semi-structured interviews were conducted in-person and by telephone. We recruited participants based on consecutive sampling of completing participants until data saturation was achieved. The interviews were conducted by investigator (MW), who had not previously never met the participants and was not involved in the planning of the intervention. The interview guide included questions on: barriers and facilitators of program adherence; telehealth delivery methods and frequency of contact; usability of the program; goal setting, self-monitoring, behavior change; and experiences (Appendix L). Modification of the interview guide occurred after each interview to broaden scope of the data collected. Interviews were audio-recorded and transcribed verbatim.

7.6 Data analysis

The sample size was determined for the purpose to inform a future studies. Therefore, a target of 30-40 participants per arm should allow for meaningful and reliable data which can be used to power future trials.[26] Quantitative data were analyzed using simple descriptive statistics (counts and percentages). To determine the difference in the utility and acceptability between the two study groups, a standard Chi square test was used with a significance level determined as $p < 0.05$. Statistics were conducted in SPSS Statistics for Windows (version 22.0. Chicago: SPSS Inc.) and Microsoft Excel.[21] Inductive content analysis[27] of the semi-structured interview transcripts regarding acceptability of the intervention was conducted by a researcher (MW) who was not involved in quantitative data planning, collection and analysis. After familiarization with the data, an open coding approach was adopted to identify, develop and finalize categories and subcategories within the data. A dietitian and qualitative researcher (DR) familiar with the data then finalized and confirmed emerging categories that were relevant to the process evaluation. Verbatim quotes were collected and used to represent attributes demonstrated for both the feasibility and acceptability of the ENTICE-CKD program. Microsoft Word[28] was used to facilitate data management (tables) and basic content analysis (comments relating to attributes demonstrating feasibility and acceptability) of data.

7.7 Results

7.7.1 Characteristics of participants

The baseline characteristics of the participants are reported in Table 7-3. Of the 80 participants who completed their baseline visit, 64% were men and had a mean age of 62 years. The stage of CKD varied within the sample, with 31% having stage 3a (eGFR 45-59ml/min/1.73m^2), 44% stage 3b (eGFR 30-44ml/min/1.73m^2) and 25% stage 4 (eGFR 15-29ml/min/1.73m^2). The most common comorbidities were hypertension (81%) and diabetes (39%) (Table 5). Baseline health literacy was good in over 90% of all participants. Randomization was effective at distributing all measured demographic characteristics.

Table 7-3: Demographics of participants whom completed the six month ENTICE-CKD pilot study.

Characteristic	**Intervention group** (n=41)	**Control group** (n=39)
Male, n (%)	**26 (63%)**	**25 (64%)**
Age (years)	**62.5 ± 12.3**	**60.5 ± 13.0**
Stage of chronic kidney disease		
3a	10 (25%)	15 (38%)
3b	19 (46%)	16 (41%)
4	12 (29%)	8 (21%)
Body Mass Index, kg/m^2	33.4 ± 6.7	31.0 ± 6.4
Hypertension	34 (83%)	31 (80%)
Diabetes	15 (37%)	16 (41%)
Active smoker status	21 (51%)	16 (41%)
Ethnicity		
Asian	2 (5%)	1 (3%)
Caucasian/European	37 (91%)	32 (82%)
Indigenous	1 (2%)	0
Other	1 (2%)	6 (15%)
Education		
Lower than 10th grade	17 (42%)	12 (32%)
Up to 12th grade	4 (10%)	10 (26%)
Tertiary educated	20 (47%)	16 (41%)
Socio-economic status		
High	27 (66%)	25 (64%)
Health Literacy		
Good	37 (90%)	36 (92%)

7.7.2 Reach and retention

Participants were recruited between November 2016 and May 2017, from Gold Coast (43%), Sunshine Coast (31%) and Brisbane (26%) hospitals. The flow of participants through the ENTICE-CKD study is shown in Figure 7-2. A total of 228 potentially eligible individuals were approached and invited to participate, of whom 80 participants (35%) were recruited to the ENTICE-CKD trial. Of the 146 individuals who declined to participate, not interested/other reasons were the most commonly stated reasons for non-participation (49%), followed by time commitment issues (14%), medical reasons (11%) and travel limitations to make study visits (11%). Additional reasons why people chose not to participate included: already feeling healthy (5%), already seeing a dietitian (5%), believed the intervention did not fit their current lifestyle (3%) or preferred not to use technology (1%). A further two individuals consented to the study but did not attend a baseline visit and were therefore not randomized to a treatment group.

Seventy-six (95%) of all randomly allocated participants completed the six-month telehealth program. A total of four (5%) participants withdrew from the study. All the withdrawals occurred in the first three months of the program. Three of the four participants who withdrew were from the intervention group (two were unable to be contacted and therefore did not commence the program, and one participant was unable to continue due to a family illness). The sole participant who withdrew from the control group did not report a reason for doing so. There were no appreciable differences in the demographics of those participants who dropped out compared to those remaining in the trial.

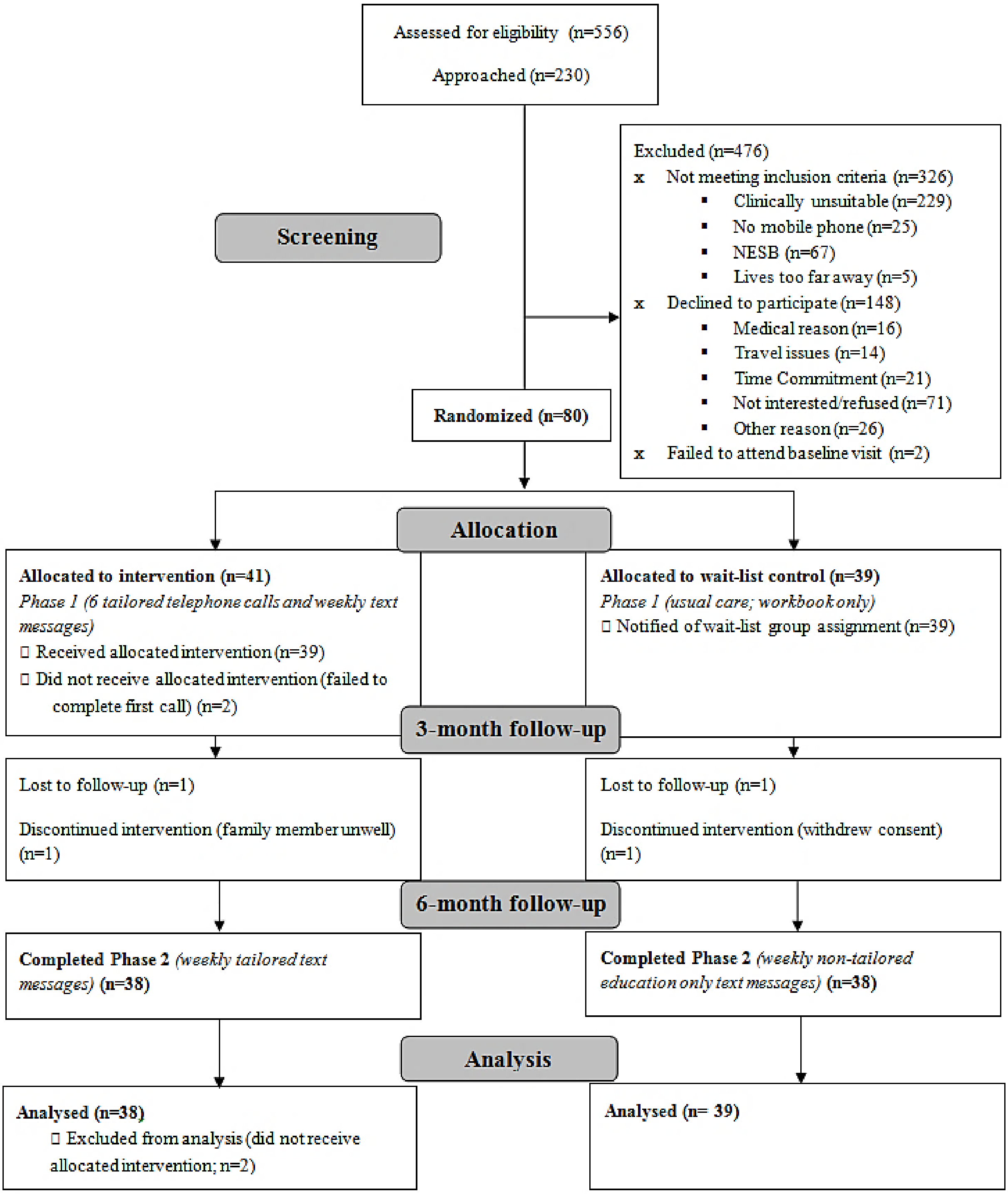

Figure 7-2: Consort flow diagram showing the flow of participants through the ENTICE-CKD study

7.7.3 Intervention delivery

Table 7-4 shows the adherence to the planned delivery of the telephone and text message components of the ENTICE-CKD intervention. The delivery of the scheduled telephone calls was conducted according to protocol with 90% of planned calls being completed as scheduled. The mean duration of the first intervention call was 45.5±10 minutes (range 28 to 75 minutes). The mean length of the subsequent five calls was 24±10 minutes (range 2 to 62 minutes).

Table 7-4: Delivery and response of fortnightly telephone calls and text messages in ENTICE-CKD.

	Intervention group		**Control group**
TELEPHONE CALLS	Phase 1	Phase 2	Phase 2
Planned	234	-	-
Actual	225	-	-
Call attempts	290	-	-
Missed calls, n (%)	9 (3)	-	-
Duration of initial calls, mins (mean± SD)	45±10	-	-
Duration of follow up calls, mins (mean ± SD)	24±10	-	-
Call scheduling text messages outgoing	245	57	0
TEXT MESSAGES – outgoing			
Total intervention texts sent, per fortnight	1371	1980	1634
Educational[a], median(range)	2(0-6)	4(0-8)	6(0-13)
Goal check[b], median(range)	2(0-4)	3(0-5)	-
Self-monitoring[c], median(range)	0(0-2)	2(0-5)	-
TEXT MESSAGES – incoming			
Total text responses	437	608	55
Recognized goal check responses, n (%)	174 (39.8)	226 (37.2)	0
Unrecognized responses	263	382	55
Requiring tailored text reply from coach, n (%)	7 (2.7)	18 (4.7)	2 (3.6)

[a] Outcome expectations (providing information on consequence)
[b] Self-regulation
[c] Self-regulation (facilitate planned behavior change

A total of 4,985 intervention text messages were sent to ENTICE participants. The median number of text messages sent to participants was within protocol for both groups, with intervention participants receiving a median of four text messages per fortnight in phase 1 and seven per fortnight in phase 2. Control participants received a median of six non-tailored education-only text messages per fortnight in phase 2 (Table 7-4). The total number of incoming text messages (replies from participants) was 1,100 (Table 7-4), 36% (n=400) triggered the appropriate goal-check reply, 3% (n=31) required the dietitian coach to send a tailored text message to address the concern raised by the sender and 61% (n=669) required no reply.

7.7.4 Intervention adherence

A total of 38 participants (95%) completed at least five calls, and 36 (90%) completed all six calls. Two participants (5%) never received a telephone call. Goal setting was completed by all participants in the first call as planned, with 95% of the participants setting two or more goals. The coaches' call logs showed that, throughout the program, participants continued setting new goals with 10 (26%) updating at least one goal in call two and 22 (61%) updating at least one goal throughout the remaining four calls (Table 7-5).

A total of 29 (76%) participants showed evidence of self-monitoring by the second call, which was sustained throughout phase 1 of the intervention. Evidence of implementation intentions indicated that the majority of participants (82%) needed at least two calls to begin putting planned dietary intentions in place. This number continued to rise over the next four calls to 97% by the end of phase 1 of the intervention.

Table 7-5: Participant adherence to the ENTICE intervention[a].

Adherence	Call 1	Call 2	Call 3-6
Total planned calls	39	39	156
Calls delivered, n (%)	39 (100)	38 (97)	148 (95)
Number of missed calls, n (%)	0	1 (3)	8 (5)
Due to withdrawal from trial			2 (1)
Due to travel			2 (1)
Other[b]		1 (3)	4 (3)
Goal setting, n (%)	38 (100)	10 (26)	23 (61)
1 goal	2 (5)	8 (21)	12 (32)
2 goals	36 (95)	2 (5)	7 (18)
3 goals	N/A[c]	N/A[c]	1 (3)
4 goals	N/A[c]	N/A[c]	3 (8)
Self-monitoring, n (%)	22/38 (58)	29/38 (76%)	29/38 (76)
Implementation intentions, n (%)	14 (37)[d]	31 (82)	37 (97)
Yes	24 (63)[d]	7 (18)	1 (3)
No			

[a] – Data are presented as *n (%).*
[b] – 1 participant decided to get tailored text messages only following call 1
[c] - In each call only 2 goals could be set or updated.
[d] - Implementation intentions were not expected to be evident in the first call

7.7.5 Acceptability

7.7.5.1 Utility and acceptability

There were several differences in ratings for utility and acceptability between the intervention (tailored-text) group compared to the non-tailored education-only text message (control) group (Table 7-6). Some participants agreed (responses for ‘agree’ and ‘strongly agree’) that the text message component: supported their dietary change (intervention 100%; 69% control, p=0.003); provided motivation to change their diet (intervention 75%, control 50%; p=0.03); and led them to a healthier diet (intervention 81%, control 61%, p=0.06). There were no other differences observed in the utility of the text messages between the groups. The majority of text messages were saved and not deleted (77% overall), and 62% were shared with family, friends or health care providers across the two study groups. Acceptability of the text messages was assessed as highly acceptable with 78% of participants reporting that the characteristics of the text messages (language, frequency, program length, time of delivery) were satisfactory.

Table 7-6: Utility and acceptability of ENTICE-CKD text messages by participant group[a].

Characteristic	Tailored text messages	Non-tailored text-messages
Usefulness and understanding		
Q1 - Useful in supporting dietary change	100%	69%**
Q2 - Messages were easy to understand	100%	100%
Influence on motivation and behavior change		
Q3 - Messages motivated change	75%	50%**
Q4 - Healthier diet due to messages	81%	61%
Q5 - Exercise increased due to messages	38%	33%
Message saving and sharing		
Q6 - Percent of messages read	100%	100%
Q7 - Saved messages	81%	72%
Q8 - Shared messages	56%	67%
Family member	71%	74%
Friend	12%	10%
Health provider	12%	10%
Appropriate message characteristics		
Q9 - Suitable language	100%	100%
Q10 - Texts were not too regular	94%	86%
Q11 - Program length (six months)	88%	78%
Q12 - Appropriate time of the day/night	100%	94%

[a] - Response rate for this survey was 73 out of 80 participants (91%), tailored text messages (n=43), non-tailored text messages (n=39).
** - p<0.01 between groups

7.7.5.2 Attributes of feasibility and acceptability

Twenty-one intervention participants were interviewed upon completion of phase 1, either by telephone (n=20) or face-to-face (n=1). Interviews ranged from 20 to 96 minutes (mean 49 min). Overall, participants had positive experiences with the ENTICE-CKD trial. Attributes of the discussions are described in nine categories within components of acceptability and feasibility (Table 7-7). The acceptability categories discussed by participants were: acceptable alternative to clinic, preference for voice communication, regular contact via text message, and personalized messages valued. In contrast, the categories described under feasibility were: program integrated into lifestyle, diverse delivery modes, social accountability, responding to dietary advice, and infeasible elements beyond intervention. Participants emphasized the importance of social accountability; all participants expressed benefit from the relationship built with their coach. Participants identified benefits from telehealth delivery of the intervention, with the majority expressing preference for telehealth over face-to-face interventions. They appreciated the personable, bidirectional conversation of the calls. The degree of usefulness of text messages was rated variably by different participants, although no participants described the content or delivery of text messages negatively. Messages that were perceived to be personalized were preferred for both calls and text messages. Participants felt that receiving information via more than one delivery mode was helpful for making diet changes. Some participants discussed challenges which were not addressed by the ENTICE-CKD intervention, such as participants not being easily able to implement routine dietary behaviors whilst travelling, or those lacking social support outside of the program.

Table 7-7: Acceptability and feasibility of ENTICE-CKD program at completion of phase 1 (intervention group): qualitative content analysis of semi-structured interviews (n=21).

Category	Attributes	Quote
Acceptability		
Acceptable alternative to clinic	Overcomes clinic wait times, transport logistics Flexibility of phone call appointment times Preferred talking from a familiar environment and not feeling rushed No identified disadvantages of telehealth communication vs face-to-face Building rapport with coach	"At home I'm more relaxed and I have the book in front of me and I was able to jot down anything that was important, if I was at the hospital there's so many people around and you don't feel very relaxed, you feel like everyone is listening to your conversation, so you don't say personal information" Female, 69
Preference for voice communication	More benefit from voice calls Frequency of fortnightly phone calls	"I found the calls better than the texts … they were more personable and kept me on track" Female, 68
Regular contact via text message	Text messages were an acceptable mode of communicating information Preference for receiving text messages with personal encouragement and general tips All text messages were acceptable	"We solved a lot of my little issues, and it's given me a lot better understanding, and you know the more you think about it and communicate about it, ah the better it is" Male, 71

Category	Attributes	Quote
Personalized messages valued	Health professional expertise Usefulness of coordinated nutrition advice Removal of multiple conflicting nutrition recommendations	"It's given me simple tasks, simple methods, or methodologies, to improve the situation, and they're not a whole lot of gobbledygook, just basic stuff that we can understand." Male, 65
Feasibility		
Program integrated into lifestyle	Length of phone calls easily accommodated 12-week telephone intervention enough time for change Self-monitoring the behavior of choice	"As long as you're getting information backwards and forwards, that's the more important thing than the length of the call, it's what you're getting out of it" Male, 78
Diverse delivery modes	Active learning from a range of understandable delivery modes Hard copy workbook as reference tool Receiving explanations develops understanding and awareness of reasons for dietary change Quantifiable dietary recommendations (food groups, "good vs bad" foods, portion sizes, sodium levels)	"You've got to eat these foods, food groups and that, but you don't actually know the right quantities … this program shows it to you and it's like, it's teaching someone how to walk again" Male, 46 "The book I think was brilliant, because you've got that to go back through all the time, well any time you're doubtful you've got thoughts, you just look at the book, I did, I still do it" Male, 64
Social accountability	Supportive relationship with one coach allows progressive dietary change Frequent reminders and reinforcing goals Interaction with coach via text messages	"If I didn't have the phone calls from [my coach] once a fortnight I probably wouldn't have taken it as serious as I have" Male, 65 "The support, even just texting and that, it's still, you know someone's doing it. It's, it just makes you feel better as a person, to know someone cares" Male, 64
Responding to dietary advice	Small changes at a time Practical strategies, manipulating environment to support behaviors, skill development (label reading) Setting goals and finding satisfaction in quantifiable outcomes (e.g. portion sizes, food group servings)	"The program is delivered in segments, you're just having a bit of information at a time, so it's not overwhelming" Female, 68 "I was astounded at the salt content of it all, so when I read that I immediately stopped all salt that I put on my plate … I've not had salt since, so that was 3 months ago" Male, 65

Category	Attributes	Quote
Infeasible elements beyond intervention	Physical comorbidities a barrier for lifestyle component of program Lack of support from others with poor understanding or low interest Unstable or unsupportive environment for creating healthy habits	"I have just been moving around a lot more and not in a stable environment of being in familiar surroundings, being unable to replicate … the menus … due to my transient nature of where I am presently" Male, 46

7.8 Discussion

This mixed methods process evaluation study within a randomized controlled trial evaluated the feasibility and acceptability of the ENTICE-CKD telehealth coaching program to promote healthy eating among people with moderate CKD. The ENTICE-CKD program was a feasible intervention that was delivered according to protocol and enabled participant adherence. The tailored telephone calls and text messages were acceptable to participants in this pilot. In contrast, the acceptability varied for those in the non-tailored education-only text message (control) group.

The successful recruitment and retention of participants enrolled in the ENTICE trial demonstrated feasibility. Although it is important to consider the trial only had a 35% recruitment rate, the feasibility was strengthened by the successful recruitment in the anticipated six-month recruitment period and very low attrition rate (5%) at six-months. Attrition is a common problem in studies of self-management in CKD, which is reported as between 11 to 39%, and which reduces the certainty of findings, particularly given the often underpowered sample sizes of trials of lifestyle interventions in CKD.[29]

The intensive coaching intervention had a high call completion rate (90%) and high intervention adherence. This is similar to the 90% call completion rates reported in other telehealth studies in weight management,[30] breast cancer,[31] younger adults in the general population,[32] and CKD studies.[33] A study involving 436 participants with CKD in the UK, who received a combination of interactive web-based resources and telephone follow-up demonstrated successful recruitment, retention and intervention satisfaction.[33] There was no specific dietary education provided to participants in that study, however the community support intervention, provided through a workbook, online portal, and telephone follow-up demonstrated a 69% recruitment rate, and had 85% retention at the six-month follow up. Participants reported over 80% usefulness for the workbook, 62% for the telephone calls and 23% for the interactive website.[33] Considering the limited evidence on lifestyle interventions in CKD specifically, the findings from this trial the feasibility of using telehealth coaching to support the dietary self-management of CKD.

The ENTICE-CKD program made participants feel supported and motivated for dietary change. However, this was more strongly indicated by participants who received the tailored intervention program, as opposed to the control group who received non-tailored education-only text messages. These results suggest that a tailored approach to text messaging may be important to patients with, as it may facilitate the support and regular interaction for dietary changes.[7] Participants felt that the frequent contact via calls and text messages reinforced rapport and built a supportive relationship between participant and coach, which in turn, enabled stronger social accountability and progressive dietary change.

Overall, there is limited evidence on the acceptability of telehealth dietary interventions in CKD.[34] A pilot study in 47 CKD participants demonstrated over 80% user adherence and satisfaction with a smart-phone self-management support program to support the self-monitoring of blood pressure, medications, symptom recognition, and biochemistry.[35] In contrast, another study found that text-message based interventions were the least preferred telehealth intervention for medication monitoring by CKD participants, compared with web-based or personal digital assistant-based applications.[36] The Effects of Sodium Modification on Outcome (ESMO) study, a three-month self-management intervention in 138 adults with CKD which provided one-to-one sessions and telephone support, demonstrated relatively high (63%) satisfaction from participants. It has been postulated that a key factor for the high acceptability of the ESMO intervention was the patient-engagement utilized in the design of the trial.[37] This was an approach also taken in the ENTICE-CKD study. We have previously found that patients with CKD have been confused by dietary advice and need more frequent contact to support dietary change.[9] They were willing to participate in telephone calls and receive text messages, as these were viewed within their comfort zone and levels of digital literacy,[9] but also raised concerns about the credibility, safety, and lack of personalization in mobile apps and internet modalities. The ENTICE-CKD program was developed from the key results in this focus group study, which assured a patient-centered approach.[38]

Previous thematic synthesis has shown that people with CKD experience many challenges in relation to achieving their dietary and fluid recommendations. People express a preference for regular coaching, feedback and monitoring to help them understand dietary information and become confident in their ability to self-monitor and manage such changes.[7] The ENTICE-

CKD intervention fostered incremental dietary changes, where each call was dedicated to an individual topic, as well as being tailored and flexible for participants' goals for change. These attributes may also explain the difference observed in the acceptability compared to the non-tailored education only (control) intervention.

There are limitations to this study. As we had a 35% recruitment rate, the feasibility and acceptability only relate to the participants enrolled in this pilot, thus the feasibility for the uptake of the program in clinical practice is uncertain. Furthermore, the baseline health literacy was 'good' in over 90 percent of our participants, which is likely greater than the health literacy of the wider CKD population,[39] therefore the generalizability of the results to people with lower health literacy is uncertain. We also acknowledge that we captured the individual participant adherence to the intervention using qualitative methods rather than validated surveys. However, given the primary outcome of feasibility, qualitative methods were used to minimize the over-use of self-report surveys and participant burden and this was an exploratory measure of intervention adherence only. Using this method, we were able to capture to reasons for adherence (and non-adherence). We also did not recruit children into the ENTICE-CKD study, so our results are not generalizable to children with CKD. Finally, we did not interview participants in the non-tailored education-only (control) group, and thus could not ascertain the reasons for lower acceptability compared with the intervention group.

In conclusion, the ENTICE-CKD dietary coaching program is a feasible and acceptable intervention for adults with stage 3- 4 CKD. The program facilitated self-monitoring and encouraged the adoption of goal setting throughout the intensive coaching period. Findings from this study are promising for the use of telehealth to modify dietary practices in future clinical practice and research. However, longer-term studies are needed to determine the safety, clinical effectiveness, and sustainability before the wider implementation of the ENTICE-CKD program is appropriate. This process evaluation can be used by clinicians to inform frequent and structured contact through telephone-based and text message platforms to support the complex dietary change required for CKD self-management.

7.9 References

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Chapter 8 – A dietary coaching program to improve dietary quality and clinical outcomes in CKD: Results from a pilot randomized controlled trial

8.1 Preface

Chapter 7 demonstrated the ENTICE-CKD program to be feasible and acceptable to people with stage 3-4 CKD. The ENTICE-CKD program was delivered to protocol, had good participant adherence, and low attrition. Furthermore, the participants in the intervention had high acceptability of the text messages supporting a healthy diet (100%) and motivating them to eat healthier (81%). However, the process evaluation reported in Chapter 7 is not able to show whether the ENTICE-CKD program leads to significant improvements in measures of diet quality or clinical parameters (including body weight, waist circumference and blood pressure).

Chapter 8 reports on the safety and effectiveness outcomes from the ENTICE-CKD study across the six-month study duration. The ENTICE-CKD study was a pilot study to primarily test its feasibility and therefore many of the effectiveness outcomes are underpowered. However, these exploratory results can be used to both inform and power a future randomised controlled trial.

8.1.1 Publication status

This chapter contains a draft manuscript to be submitted to the peer-reviewed journal the *American Journal of Kidney Disease*. This chapter is formatted to a consistent thesis style. However, the grammar, headings, and references (in-text and bibliography) are unaltered in accordance with the journal publishing guidelines.

Citation: **Kelly JT**, Conley M, Johnson DW, Hoffmann TC, Tong A, Craig J, Reidlinger DP, Reeves M, Howard K, Krishnasamy R, Kurtoki J, Craig J, Palmer S, Campbell KL. A dietary coaching program to improve dietary quality in CKD: The ENTICE-CKD randomized controlled trial. [Unpublished].

8.2 Abstract

8.2.1 Rationale & Objective

The dietary self-management of chronic kidney disease (CKD) requires regular follow-up to support dietary change. This study evaluated the safety and effectiveness of a 6 month telehealth-delivered intervention on improving diet quality in people with stage 3-4 CKD.

8.2.2 Study design

Two-arm pilot randomized controlled trial.

8.2.3 Setting & Participants

Eighty stage 3-4 CKD (GFR 60-15/min/1.73m^2) participants, recruited from 3 nephrology units in Australia.

8.2.4 Intervention

The intervention group received fortnightly phone calls for 3 months and tailored text messages for 6 months to achieve a diet consistent with the Australian Dietary Guidelines. The control group received usual care for 3 months followed by a non-tailored education-only text message intervention for 3 months.

8.2.5 Outcomes

The primary outcome was change in diet quality (measured by the Australian Recommended Food Score [ARFS] and food groups). Secondary outcomes were change in weight and blood pressure.

8.2.6 Results

No significant change in ARFS or blood pressure was observed at any time point. The intervention group participants significantly increased the proportion of calories from core foods consumed (5.2% [95% confidence interval (CI) 0.6, 9.9]), vegetable intake (1.4 serves/day [CI 0.3, 2.1]), dietary fiber (5.5g/day [CI 2.7, 8.2]), and reduced body weight (-1.7kg [CI -3.1, -0.3]) at 3 months compared to control group participants. At 6 months, the proportion of calories from core foods remained significant (4.3% [CI 0.3, 8.2]). No intervention-related safety concerns occurred throughout the study.

8.2.7 Conclusions

Telehealth coaching improved dietary intake of core foods, vegetable and fiber intake, and decreased body weight at 3 months in this pilot study. Extended contact sustained core food

intakes at 6 months. A larger and longer term randomized trial is required to determine the effect of this intervention on quality of life, renal, and cardiovascular outcomes.

8.2.8 Funding

Support grant from the Australasian Kidney Trial Network and Bond University.

8.2.9 Trial Registration

ACTRN12616001212448.

8.2.10 Keywords

Diet, telehealth, chronic kidney disease, pilot, trial

8.3 Introduction

Chronic kidney disease (CKD) affects over 10% of the world's population,[1] and represents a significant public health challenge.[2,3] Dietary modification is a key management strategy in CKD. Addressing dietary quality through food based education may be more comprehendible than traditional nutrient approaches in CKD, as it focuses less on restriction and is more patient-centered.[4] Furthermore, improving diet quality through adopting a healthy dietary pattern has been associated with a 27-35% improved survival in populations with established CKD.[5,6] However, evidence to show how people with CKD can be best supported in improving diet quality is unknown.

The current models of dietetic care are focused on face-to-face appointments which are known to be limited in non-dialysis CKD populations, resulting in a lack of individualized follow-up that is required to achieve complex dietary change.[4,7] Renal clinicians find it challenging to provide this individualized follow-up in traditional practice settings due to geographical, time, and financial barriers, associated with providing dietary care consistent with current renal nutrition guidelines.[8,9] To determine whether adopting a healthy dietary pattern may attenuate the progression of CKD on a sufficient scale for a randomized controlled trial (RCT), alternative delivery modes and settings that are safe and effective in supporting dietary management are needed.

An alternative to face to face appointments is telehealth which includes telephone coaching and other m-Health approaches. Telephone coaching is a basic form of telehealth which has been shown to be effective at promoting adherence to complex dietary recommendations in chronic disease.[10] In CKD populations, telephone coaching in combination with one-on-one support can reduce dietary sodium intake,[11] and increase knowledge of self-management behaviour.[12] M-Health, which extends more broadly to the use of mobile phones for healthcare delivery, is perceived as flexible and cost-effective[13] and can improve diet quality in people with coronary heart disease.[14] From recent patient engagement studies, people with CKD are open to using these methods for their dietary self-management.[4,15] However, no study has established whether telephone coaching interventions can improve diet quality in people with stage 3-4 CKD. The aim of this pilot study was to establish the safety and potential effectiveness of a telehealth-delivered intervention for improving diet quality in people with stage 3-4 CKD.

8.4 Methods

8.4.1 Study design

The ENTICE-CKD study was a single-blinded, two-arm pilot randomised-controlled trial. Participants were recruited over a 6 month period across three large teaching hospitals in Australia. This trial was conducted according to the Consolidated Standards of Reporting Trials (CONSORT) framework[16] and reported in-line with the Template for Intervention Description and Replication (TIDieR) checklist.[17]

8.4.2 Participants

People were eligible to participate if they were aged over 18 years of age, with stage 3-4 CKD (eGFR 15-59 ml/min/1.73m^2), had access to a mobile phone, and provided written informed consent. People were also considered eligible if they had previously received a kidney transplant greater than 12 months prior to recruitment, and their nephrologist deemed them safe to participate. People were excluded if they were either treated with dialysis, were non-English speaking, or deemed unsafe to participate by their nephrologist. Potential participants were screened for eligibility by a local site investigator or research nurse from daily outpatient appointment lists and relevant hospital databases. Following discussion with their treating nephrologist, people were approached and invited to participate. If people were unable to be contacted at their outpatient appointment, they were mailed a written invitation to participate with a phone number to contact if they were interested.

8.4.3 Randomisation and allocation concealment

Randomization schedule was created in RedCap[18] and allocated on a 1:1 ratio, stratified by recruitment site and diabetes status by computer-generated random numbers to conceal allocation from recruiters and site investigators. Site investigators involved in recruiting participants and outcome assessment were not aware which group participants were randomized to and remained blinded for the duration of the study. Ethics was approved by the Metro South Health Service District Human Research Ethics Committee (EC00167) and Bond University Human Research Ethics Committee (EC00357). The trial was prospectively registered (ACTRN12616001212448).

8.4.4 Study treatment

The detail of the intervention treatment is outlined in Table 8-1. Primary care physicians and treating nephrologists retained full responsibility over their patients’ medical care at all times during the study. The ENTICE-CKD program was adjunct to the usual care participants received. In Australia, usual care typically involves medical care with 3-monthly follow-up of patients with stage 4 CKD, and 3-6 monthly follow-up for stage 3 CKD patients. People with stage 3-4 CKD do not typically get dietary consultation with a dietitian, unless there is clinical indication.[19]

Following a face-to-face baseline assessment with the local site investigator, all participants received the ENTICE-CKD workbook (summarised in Table 8-1), which was designed by renal dietitians, with extensive academic, clinician, and consumer input. Participants randomised to the intervention completed the telehealth intervention in two phases (Figure 8-1). The first phase involved individualized, telephone-based coaching every fortnight for 3 months (6 calls total). During each coaching call, accredited practising dietitian (registered dietitian equivalent) with additional training in behaviour change, motivational interviewing and renal nutrition worked collaboratively with patients to develop achievable goals. Each participant was coached to reduce dietary sodium intake to < 100mmol/day (or <2300mg) and improve diet quality in line with the Australian Dietary Guidelines.[20] The dietiian (coach) used motivational interviewing techniques, and could tailor the intervention to the individual's set goals, co-morbidities, and current stage of behavior change. The call content was guided by Bandura's Social Cognitive Theory,[21] embedding core principles of healthy eating patterns into practical strategies for behavior change. Each call was semi-scripted, designed in-line with each section of the workbook, and structured based on the 5As framework (Assess, Advise, Agree, Assist, Arrange).[22] In addition to telephone coaching, intervention participants received 2 to 8 fortnightly text-messages to support the telephone coaching in phase 1, including goal checks, self-monitoring reminders and dietary education at a frequency determined by participant's preference (see Table 8-1).

Table 8-1: Outline of the intervention description according to the TIDieR checklist.

Item Name/Number	Item Description
Item 1: Brief name	
ENTICE-CKD	
Item 2: Why	
Diet pattern intervention has not been evaluated in RCT in people with stage 3-4 CKD. Telehealth may facilitate the level of education and health professional contact to achieve a complex intervention in CKD, but this has not been evaluated in RCTs to date. For more detailed description of the background, see introduction (section 8.3)	
Item 3: What	
ENTICE-CKD program workbook (available in Appendix J; sections outlined below)	
About ENTICE	Introduction page "The focus of the ENTICE program is to help you make gradual changes to your eating and physical activity habits that work for YOU – changes that become lifelong."
Section 1: Setting your goals and keeping track	"Use the following steps every time you set a SMART goal…"
Section 2: Eating well for healthy kidneys	"The ENTICE program will help you to gradually make changes to your diet to meet the daily recommended serves of fruit, vegetables and wholegrain breads/cereals."
Section 3: Active living	"Participating in regular physical activity and reducing sitting time is very important for your health and well-being."
Section 4: Why is healthy eating important for my kidneys?	Did you know? "Less than 4% of the Australians meet the recommended daily intake for vegetables. Research has shown that increasing your intake of vegetables by as little as ONE serve per day can help you live longer and stronger."
Section 5: Plan for success	"There are a number of things that affect what we eat and our overall energy intake. It is important to be aware of, pay attention to and plan for: How you eat; Where/why you eat?
Section 6: Self-monitoring and setting goals	Smart snacking Reflections Tracking my food intake
Section 7: Additional healthy eating resources	Useful websites; Healthy recipes Useful apps for mobiles or tablets High/low potassium/phosphate foods (if required) Healthier verse unhealthy takeaway options
Item 4: What - procedures	
Intervention: Each call was designed in-line with each section of the workbook, and structured based on the 5As framework (Assess, Advise, Agree, Assist, Arrange).[22] Diet: Reduce dietary sodium intake <100mmol/day and improve diet quality in line with the Australian Dietary Guidelines.[20] **Intervention calls** **Call 1** • Welcome to ENTICE-CKD • Information about the program • Feedback on baseline outcome measures • Complete Section 1 – goal setting • Discuss section 6 – self monitoring • Begin section 2 - introduction the five food groups	

Item Name/Number	Item Description

Call 2

- Revisit goals
- Recap Dietary Guideline food groups – answer any questions
- Continue section 2 – (plate model, snacks, salt, label reading, potassium and phosphate)

Call 3

- Revisit goals
- Answer any questions on healthy eating
- Complete section 3 – Active living

Call 4

- Revisit goals
- Revisit any questions about active living/ healthy eating
- Complete section 4 – Why is healthy eating important for my kidneys
- Complete section 5 - planning for success - how why and where you eat and managing slips

Call 5

- Revisit goals
- Answer any dietary or Active living questions
- Discuss section 7 - additional information / resources

Call 6

- Revisit goals
- Revisit any questions participant may have
- Discuss where to from here
- Adjust text message frequency if desired

Text message component

			Intervention		Control	
Text message type	**SCT construct**	**Example text**	Phase 1	Phase 2	Phase 1	Phase 2
Education	Outcome expectations	Dietary fibre intake reduces ur cholesterol levels and controls ur blood sugar. Include wholegrain breads & cereals, fruits & veg regularly	2-6	1-4	NA[a]	6-8
Self-monitor	Self-regulation	Hi [name], are u keeping track of ur fruit/vegetable intake every day? Remember ur goal to have 5 serves this week	0-2	1-4	NA	NA
Goal check	Self-regulation	Hi [name], did u reach ur goal to eat 5 fruits/vegetables 4 times this week? Text me back yes or no to let me know	2	2-4	NA	NA
Education (Safety protocol)	Low potassium diet	Choose high fibre, low potassium breakfast cereals. Good choices are Multigrain Weetbix, Rolled Oats, Guardian, Oatbritz, Special K	0-2[a]	0-2[a]	NA	0-2 [a]

Item 5: Provider

Accredited practicing dietitians (RD equivalent) with additional training in behavior change, motivational interviewing and renal nutrition.

Item 6: How

Phase 1 (month 0-3)	Intervention: One-one coaching provided through 6 fortnightly phone calls, and tailored text messages at a frequency requested by the participant (TIDieR item 4 – Text message component). Control: Usual care only (section 8.4.4 - Study Treatment & 8.4.5 – control group).

Item Name/Number	Item Description
Phase 2 (month 3-6)	Intervention: Tailored text messages at a frequency requested by the participant (TIDieR item 4 – Text message component). Control: Non-tailored education-only text messages at a frequency requested by the participant (TIDieR item 4 – Text message component).
Item 7: Where	
Participants were in locations of their choosing as the intervention was delivered by telephone/mobile.	
Item 8: When and How Much	
Phone calls: Intervention group participants received fortnightly phone calls for 3 months Text messages: Intervention participants received fortnightly text messages for 6 months. Control group participants received text messages for 3 months (TIDieR item 4 – Text message component).	
Item 9: Tailoring	
Phone calls: Coaches could tailor the dietary guidelines to participants' individual comorbidities and goals. Coaches documented tailoring in call logs. Text messages: Tailored text messages were tailored to participants' names, set goals and barriers to achieving each goal (examples can be seen under TIDieR item 4 – Text message component). Non-tailored education only text messages were education only and contained no tailoring.	
Item 10: Modifications	
Some participants who replied to the goal check text messages in a way the system could not recognize (i.e. not a yes/no response) were giving a tailored goal check reply message instead of the automatic system generated reply (see Chapter 7 for more details). No other modifications were made to the intervention during the course of the study.	
Item 11: How well: planned	
Reported in Chapter 7	
Item 12: How well: actual	
Reported in Chapter 7	

Abbreviations - ENTICE-CKD: The Evaluation of Individualized Telehealth Intensive Coaching to Promote Healthy Eating and Lifestyle in Chronic Kidney Disease, SCT: social cognitive theory, RCT: randomized controlled trial, NA: not applicable, TIDieR: template for intervention description and replication. [a] = Educational permutations were only available for coaches to use if a participant experienced hyperkalemia or hyperphosphataemia

Phase 2 of the intervention involved no further telephone coaching calls. Participants continued to receive the same tailored text messages as phase 1, except they were able to receive from 4 to 12 fortnightly text-messages (Table 8-1). At the end of phase 1 (3 month study mid-point), participants completed their final coaching call and discussed their preferences for the timing and frequency of the phase 2 text messages. At 18 weeks, participants received another tailoring call (no dietary coaching) to make individualized adjustments to the text message frequencies for the remaining 6 weeks of the intervention (Figure 8-1).

8.4.5 Control group

Participants randomized to the control group were wait-listed for 3 months and received 2 phases of care. In phase 1 (month 0-3), they received the same ENTICE-CKD workbook as the intervention group and continued to receive routine usual care, but no other intervention (no calls or text messages). After 3 months (end of phase 1) participants commenced phase 2 (month 3-6), which was a text-only intervention, with participants only able to choose the frequency of text messages per fortnight. The content was educational, based on the Australian Dietary Guidelines,[20] and CARI guidelines,[23] and was based on approaches used in cardiac rehabilitation, with proven success on dietary and clinical outcomes.[14]

8.4.6 Outcome assessment

All data was collected at baseline, 3 months and 6 months at each participant's recruiting hospital as shown in Figure 8-1. All participants' study visits were scheduled on separate days or hours apart to avoid the risk of contamination bias. Site investigators were blinded to treatment allocation and participants were asked not to disclose which group they had been assigned to during their study visits. Self-reported surveys were completed by participants, either on site, returned via registered post, or completed via an online email link to minimize participant burden and keep the data collection in-line with usual care as much as possible.

8.4.7 Primary outcome

Change in diet quality was captured from the Australian Eating Survey.[24] This survey is a 120-item semi-quantitative food frequency questionnaire (FFQ), which estimates daily calories consumed from the core-food groups, fiber, and sodium intake per day. The FFQ also calculates total serves of fruit and vegetables per day, however, it does not calculate the total serves of the other food groups per day (i.e. meat and alternatives, dairy, breads and cereals which feature in the Australian Dietary Guidelines[20]). The Australian Eating Survey produces its own overall indicia of diet quality, reported as the Australian Recommended Food Score (ARFS), which is a calculation of variety of fruit, vegetables, grains, dairy, meats, chicken and fish, condiments, and water consumed each day. Scores are given on a scale of 1-73, with score of <33, 33-38, 39-46, and >47 reflecting a diet score which is 'needing work', 'getting there', 'excellent', or 'outstanding', respectively.[25]

8.4.8 Secondary outcomes

Body weight (rounded to the nearest 0.1kg) and waist circumference (rounded to the nearest 0.1cm) were collected to a standard protocol.[26] Change in clinic blood pressure was measured with a calibrated digital blood pressure monitor in accordance with the recommended protocol of the American Heart Association.[27] Changes in antihypertensive medication requirements (total number, dose, class) were collected from participants and verified from patient records at each study visit. Quality of life was measured using the 'Assessment of Quality of Life' questionnaire (AQoL-4D).[28] Risk markers of kidney disease progression were collected as the estimated glomerular filtration rate (GFR) from blood serum pathology and albuminuria on mid-stream urine samples.

Screening and recruitment

↓

Randomization

Week	Intervention group	Control group
Phase 1	Baseline Visit **Outcomes** • Demographics • Health literacy • Dietary intake (FFQ) • Body weight and waist circumference • Blood pressure • Medication requirement • Quality of Life • Blood Pathology (including electrolytes (Potassium) and Creatinine (to assess eGFR)) • Urinary albumin-creatinine ratio	
2 4 6 8 10	6x fortnightly telephone calls + tailored text messages + workbook	Usual Care (workbook only)
12	Mid-point visit + telephone call	
3-month visit	**Outcomes** • Dietary intake (FFQ) • Body weight and waist circumference • Blood pressure • Medication requirement • Quality of Life • Safety • Blood Pathology (including electrolytes (Potassium) and Creatinine (to assess eGFR)) • Urinary albumin-creatinine ratio • Adverse events	
Phase 2 14 16	Tailored text messages	Educational text messages
18	Telephone call	
20 22	Tailored text messages	
24	End-point visit	
6-month visit	**Outcomes** • Dietary intake (FFQ) • Body weight and waist circumference • Blood pressure • Medication requirement • Safety • Blood Pathology (including electrolytes (Potassium) and Creatinine (to assess eGFR)) • Urinary albumin-creatinine ratio • Adverse events	

Figure 8-1: Summary of ENTICE-CKD program delivery

8.4.9 Safety monitoring

Safety monitoring included the monitoring of hypertensive episodes and level of serum potassium at each visit. Participants were trained to identify symptoms of hypotensive episodes between study visits, defined as systolic blood pressure <100 mmHg or dystolic blood pressure <60 mmHg, and instructed to contact their general practitioner or specialist if symptoms arose. During fortnightly coaching calls, coaches also monitored symptoms and/or large changes in electrolyte intake. If concerns were identified, notification for follow-up was made to their general practitioner.

8.4.10 Sample size

As a pilot trial which was primarily designed to test the feasibility of the ENTICE-CKD program, a power calculation was not necessary. Instead, all effectiveness outcomes were considered exploratory and used to power a future study. It is suggested that pilot studies should target 30-40 participants in each study group to generate meaningful data for future power calculations and reliability of outcome data.[29]

8.4.11 Statistical analysis

All analyses were conducted based on the intention-to-treat principle. Univariate data were explored and assessed for normality by visual exploration and confirmed by the Shapiro-Wilk test statistic. An analysis of covariance (one-way ANCOVA) was conducted to assess the main effects of the categorical independent variable (telephone-coaching versus control; or tailored text-messages versus non-tailored education-only text messages) between groups on a single continuous dependent variable, after controlling for the effects of the baseline covariate. Categorical outcomes were assessed by the standard chi-square test. Within group changes of the two study groups were analysed using the paired-sample t-tests for normally distributed data, or Wilcox signed ranks tests for non-normally distributed data. A 2-sided p value (≤ 0.05) was considered statistically significant. Statistical analysis for effectiveness outcomes were performed using SPSS Statistics for Windows (version 22.0. Chicago: SPSS Inc.).

8.5 Results

The flow of the participants through the ENTICE-CKD study is shown in Figure 8-2. Eighty participants were randomized, and 76 participants completed the 6 month study. Randomisation was effective at distributing important demographics as shown in Table 8-2. Overall, 64% of the sample was male with a mean age of 62 years. There was equal distribution of diabetes (39%), hypertension (81%), and each stage of CKD, stage 3a (31%), stage 3b (44%) and stage 4 (25%) between the study groups. Participants had a favourable dietary intake at baseline, with an overall ARFS of 39.5 points (rated in the 'excellent' category), fruit and vegetable intake of 1.8 serves and 4.5 serves, respectively, and mean sodium intake of 2.3g per day.

8.5.1 Change in dietary intake

Table 8-3 shows the change in dietary intake over the study. The intervention significantly improved components of diet quality as reflected by an increase in calories from the core food (non-discretionary) groups at 3 months (5.2% [95% confidence interval (CI): 0.6, 9.9]) and 6 months (4.3% [CI: 0.3, 8.2]) compared to the control group (p=0.029 and p=0.034, respectively). However, overall changes in the ARFS were not significant between or within groups at 3 or 6 months. At 3 months, the intervention significantly increased vegetable intake (1.4 serves/day [CI: 0.6, 2.1]), grams of dietary fiber (5.5 g/day [CI: 2.7, 8.2]) compared to the control, however the change was not statistically significant at 6 months. There was no significant change for sodium or servings of fruit per day between the intervention and the control group.

Significant within group changes were observed in intervention group participants for the servings of fruit per day at 3 months (0.6 serves; p=0.001), and 6 months (0.4 serves; p=0.029), but not in control group participants. Both the intervention and control group reduced their dietary sodium intake (Table 8-3). The control group also increased the proportion of calories from the core food (non-discretionary) groups following the 3 month non-tailored intervention (4.4%; p=0.032), but not after 3 months of usual care only.

8.5.2 Weight and waist circumference

The intervention group participants significantly decreased weight at 3 months (-1.7 kg [CI: -3.1, -0.3]) compared to control group participants (p=0.018). There was no significant change for waist circumference between the intervention and the control group.

There was significant within group changes in the intervention for weight (-1.8 kg; p=0.0001) and waist circumference (-1.8 cm; p=0.002) at 3 months, which was sustained at 6 months for body weight (-1.5kg; p=0.023) and waist circumference (-2.9cm; p=0.001). The control group did not significantly change their weight or weight circumference at any time point (Table 8-4).

8.5.3 Blood pressure

There was no significant change between or within the groups in blood pressure in the intervention group or control group at either time point. Sixteen percent (n=6) of intervention group participants increased their total number of antihypertensive medications compared to 29% (n=11) in the control at 3 months. One participant (3%) in the intervention group decreased their total number of antihypertensive medication use compared to none in the control at 3 months. This change in the use of antihypertensive medications was significant ($\varphi=0.33$; $p=0.017$) at 3 months but not at 6 months ($p=0.1$) between the intervention and the control (Table 8-4).

8.5.4 Risk factors for kidney disease progression

There was no significant change for serum creatinine, urinary albuminuria or eGFR at any time-point, in any of the study groups (Table 8-4).

8.5.5 Quality of life

Quality of life relating to the mental health domain significantly increased at 3 months (mean difference: 0.05; $p=0.012$) and at 6 months (mean difference: 0.04; $p=0.049$) in the intervention group, but not in the control. There was no significant change between the groups for any of the quality of life domains at any time point (Table 8-5).

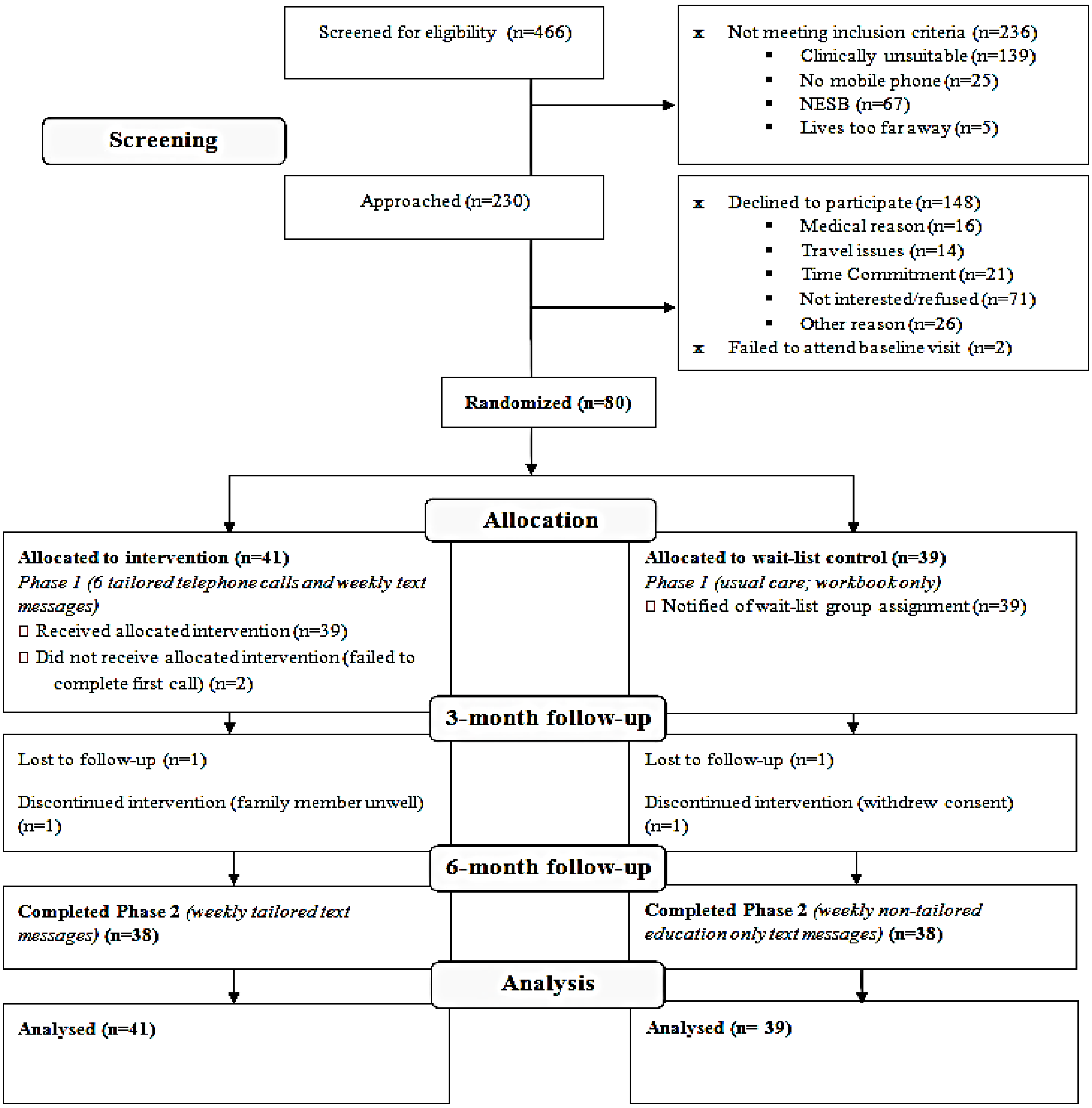

Figure 8-2: CONSORT diagram showing the flow of participants through the ENTICE-CKD study.

8.5.6 Safety monitoring and adverse events

There were no incidences of hypotensive episodes or hyperkalaemia documented throughout the 6 month study. In the first 3 months of the study, one intervention participant suffered a heart attack which was unrelated to the intervention. The participant was able to continue the intervention with no impediment, however they commenced cardiac rehab adjunct to the dietary coaching intervention. No adverse events occurred from months 3-6 months of the study.

Table 8-2: Baseline characteristics of participants in the ENTICE-CKD study.

Characteristic		Intervention n=41	Control n=39
Age, years		62.5 ± 12.3	60.5 ± 13.0
Gender, % male		63.0	64.0
Ethnicity, %			
	Asian	5.0	3.0
	Caucasian	85.0	74.0
	European	5.0	8.0
	Indigenous	2.5	0.0
	Other	2.5	15.0
Diabetes, %		39.0	39.0
CVD, %		34.0	31.0
Hypertension, %		83.0	80.0
Anti-hypertensive medications, n		74.0	73.0
	ACE	11.0	14.0
	α1-blocker	9.0	1.0
	B-blocker	13.0	17.0
	CCB	15.0	11.0
	Diuretic	18.0	15.0
	ARB	22.0	18.0
	Other	3.0	6.0
Anti-hypertensive pill count, n		92.0	87.0
Serum creatinine, µmol/L		173.4 ± 53.5	164.8 ± 61.4
eGFR		35.9 ± 11.7	39.0 ± 12.1
Systolic blood pressure, mmHg		136.4 ± 18.4	130.7 ± 18.7
Diastolic blood pressure, mmHg		80.2 ± 11.9	77.5 ± 11.0
Weight, kg		96.4 ± 22.4	90.2 ± 19.0
BMI, kg/m^2		33.4 ± 6.9	31.0 ± 6.4
Waist circumference		112.8 ± 17.5	106.9 ± 18.0
Urine albuminuria, mmol/L		120 (8.0, 442.0)	38.5 (13.0, 143.5)
ARFS		39.2 ± 18.9	39.9 ± 16.9
Proportion of energy from core food groups, %		63.0 ± 17.5	65.4 ± 13.9
Fruit, serves/day		1.5 ± 0.8	2.0 ± 1.6
Vegetables, serves/day		4.0 ± 2.1	5.2 ± 2.3
Sodium, mg		2354.8 ± 1405.3	2285.2 ± 887.3
Fibre, g		24.1 ± 9.1	26.7 ± 9.5

Data are reported as mean ± SD or Median (IQR). Abbreviations: CVD: cardiovascular disease, ACE: angiotensin converting enzyme, CCB: calcium channel blocker, ARB: angiotensin receptor blocker, eGFR: estimated glomerular filtration rate, BMI: body mass index.

Table 8-3: Changes in indices of dietary quality at 3 months and 6 months, adjusted for baseline values.

	3 months - Baseline			6 months - Baseline		
Dietary component	**Intervention n=41**	**Control n=39**	**Mean Difference**	**Intervention n=41**	**Control n=39**	**Mean Difference**
Australian Recommended Food Score	1.2 (-8.0, 5.6)	-0.4 (-6.4, 7.2)	1.1 (-6.3, 8.5)	-0.9 (-3.9, 5.8)	-2.1 (-4.4, 8.5)	0.7 (-5.6, 7.1)
Proportion of energy from core food (non-discretionary) groups, %	9.5 (13, 5.6)**	3.2 (1.0, 7.4)	5.2 (0.6, 9.9)*	9.7 (6.4, 13.0)**	4.4 (0.4, 8.4)*	4.3 (0.3, 8.2)*
Fruit, serves/day	0.6 (0.3¸0.9)**	0.1 (-0.6, 0.3)	0.3 (-0.2, 0.8)	0.4 (-0.7, 0.0)*	0.1 (-0.6, 0.4)	0.1 (-0.4, 0.6)
Vegetables, serves/day	1.3 (0.7, 1.8)**	-0.3 (-0.2, 0.8)	1.4 (0.6, 2.1)**	0.6 (-1.2, 0.0)*	0.0 (-0.7, 0.7)	0.2 (-0.6, 1.1)
Fibre, grams/day	4.6 (2.6, 6.5)**	-1.2 (-0.8, 3.1)	5.5 (2.7, 8.2)**	1.1 (-3.0, 0.7)	-0.5 (-2.2, 3.1)	0.8 (-2.1, 3.8)
Sodium, milligrams/day	-282.6 (-1.8, 567.1)	-415.1 (162.4, 667.8)*	160.8 (-150.4, 472.0)	-470.4 (157.2, 783.5)*	-375.5 (70.4, 680.6)*	-51.4 (-331.7, 229.0)

*P=<0.05; **P=<0.001

Table 8-4: Changes in clinical assessment data at 3 and 6 months, adjusted for baseline values.

	3 months - Baseline			6 months - Baseline		
Dietary component	**Intervention n=41**	**Control n=39**	**Mean Difference**	**Intervention n=41**	**Control n=39**	**Mean Difference**
Weight, kg	-1.8 (-2.6, -0.9)**	-0.1 (-1.0, 1.2)	-1.7 (-3.1, -0.3)*	-1.5 (-2.8, 0.2)*	0.1 (-1.2, 1.3)	-1.5 (-3.3, 0.4)
Waist circumference, cm	-1.8 (-3.0, -0.7)*	0.8 (-0.9, 2.5)	-0.6 (-2.5, 1.4)	-2.9 (-4.6, -1.2)**	0.8 (-1.4, 3.1)	-1.0 (-3.4, 1.4)
SBP, mmHg	-1.8 (-7.7, 4.1)	2.2 (-3.1, 7.5)	-0.9 (-7.3, 5.6)	-0.6 (-7.1, 5.9)	1.7 (-4.3, 7.8)	-0.8 (-6.9, 8.5)
DBP, mmHg	-2.7 (-5.9, 0.5)	0.4 (-2.7, 3.5)	-1.4 (-5.6, 2.8)	-1.0 (-4.2, 2.3)	-0.1 (-3.1, 2.9)	-0.9 (-3.3, 5.0)
Serum creatinine, µmol/L	-4.7 (-13.3, 3.9)	1.4 (-8.7, 11.6)	-6.6 (-19.7, 6.5)	-3.6 (-12.3, 5.1)	2.0 (-14.7, 18.7)	-6.6 (-25.0, 11.8)
eGFR, mL/min	0.8 (-1.4, 3.0)	1.5 (-0.8, 3.8)	1.1 (-2.1, 4.2)	1.3 (-0.8, 3.4)	2.6 (-0.1, 5.3)	1.4 (-2.0, 4.8)
Urine albuminuria, mmol/L[a]	86 (8, 304)	29 (8.5, 217.5)	-	89 (11, 412)	46 (10, 187)	-

Abbreviations –eGFR: estimated glomerular filtration rate, SBP: systolic blood pressure, DBP: Diastolic blood pressure, kg: kilograms, cm: centimeters mmHg: millimetres of mercury

[a]: Albuminuria is reported as median and interquartile range and is the absolute value for each time point.

*P=<0.05; **P=<0.001.

Table 8-5: Changes in quality of life at 3 months and 6 months.

	3 months - Baseline			6 months - Baseline		
Dietary component	**Intervention n=41**	**Control n=39**	**Mean Difference**	**Intervention n=41**	**Control n=39**	**Mean Difference**
Independent-living	0.02 (-0.01, 0.06)	-0.02 (-0.05, 0.02)	0.04 (-0.01, 0.08)	0.01 (-0.01, 0.03)	-0.02 (-0.05, 0.02)	0.02 (-0.02, 0.06)
Relationships	0.03 (-0.03, 0.09)	0.02 (-0.03, 0.06)	0.02 (-0.05, 0.08)	0.02 (-0.04, 0.08)	0.02 (-0.03, 0.06)	0.01 (-0.05, 0.07)
Senses	0.01 (-0.01, 0.04)	0.00 (-0.02, 0.02)	0.02 (-0.01, 0.05)	0.01 (-0.02, 0.04)	0.02 (-0.00, 0.04)	0.00 (-0.03, 0.03)
Mental health	0.05 (0.01, 0.09)*	0.03 (-0.01, 0.08)	0.04 (0.00, 0.08)	0.04 (-0.00, 0.08)*	0.04 (-0.02, 0.10)	0.02 (-0.03, 0.08)

*P=<0.05.

8.6 Discussion

The ENTICE-CKD program was a pilot RCT which aimed to establish the safety and effectiveness of a telehealth-delivered intervention for improving diet quality in people with stage 3-4 CKD. The primary finding is that the intervention was safe and intervention group participants had statistically significant improvements in important components of diet quality, reflected in the increase proportion of calories from core food groups, servings of vegetables, and dietary fiber. However, the overall diet quality metric as measured by the ARFS did not significantly change at any time point in this pilot study. Body weight significantly reduced in the intervention group compared to the control group, whereas blood pressure did not significantly change at any time point. Following 3 months of extended contact (month 3-6) the non-tailored education-only text messages (control) group significantly increased their proportion of calories from core foods consumed, however the tailored text messages (intervention) group change was significantly greater between the groups.

Improving diet quality through consuming a higher proportion of foods from the core food groups such as fruit, vegetables, fibre, legumes, and cereals, in CKD is associated with a lower risk of all-cause mortality.[30] While it is important to note that there was no significant change in ARFS as the overall diet quality metric, participants in the intervention group did improve important components of dietary quality. Participants in the intervention group consumed a higher proportion of calories from foods which came from the core food groups, and higher intake of vegetables compared to the control group participants. Previous studies have shown that consuming more fruit and vegetables is an independent predictor of lower risk of death over a four-year follow-up in Australian adults with stages 3-4 CKD (HR 0.35, 95% CI 0.15 to 0.83). People with stage 4 CKD randomised to a higher fruit and vegetable intervention have also been shown to lower metabolic acidosis, reduce blood pressure and reduce body weight, compared to a standard sodium bicarbonate prescription alone.[31]

Consuming higher intakes of fruit and vegetables also increases the intake of dietary fiber. In the ENTICE-CKD program arm, participants significantly increased their consumption of dietary fiber by over 5 grams per day. This increase in fiber takes participants mean fiber intake to over 30 grams per day, which is the recommended intake in the current dietary guidelines.[32] Meta-analysis of 14 CKD controlled-feeding trials showed dietary fiber to significantly reduces serum urea and creatinine levels.[33] Observational studies in CKD populations suggest that higher intake of dietary fiber can reduce inflammation and the risk of mortality.[34] Increasing dietary fiber intake may also attenuate imbalance in the gut microbiome, which is known to have a role in modification of protein-bound uremic toxins and a potential modifier of cardiovascular risk in CKD.[35]

Weight loss approaches are effective at improving clinical parameters in CKD. Excessive weight gain carries higher burden of cardiovascular risk and CKD progression.[36] Compared to baseline, participants in the intervention group significantly reduced body weight by 1.7kg at 3 months, which was sustained at 6 months. This is a similar finding to a recent randomized controlled trial, in which 92 CKD patients completed a reduced calorie and activity lifestyle intervention over four months. Participants in the intervention group lost 1.8kg body weight and 1.6% more in body fat compared to an exercise intervention alone.[37] Similarly in another CKD lifestyle intervention, 72 patients with stage 3-4 CKD demonstrated a combined exercise and diet program to significantly reduced body weight by 1.8kg and improve cardiovascular fitness.[38] The results of these two studies are of similar magnitude with ENTICE-CKD and may demonstrate the effectiveness of dietary coaching through telehealth to reduce body weight. However, it is important to note the between group differences were not maintained at 6 months in our study. This may be due to the study being underpowered, the control group commencing a non-tailored education-only text message intervention, or the lack of one-one coaching in the tailored text messages from months 3-6. This needs to be explored in future trials before reliable conclusions can be made.

Blood pressure is an important controllable risk factor for CKD progression but was unchanged in the ENTICE-CKD participants. Fundamentally, this study was not powered to detect blood pressure changes. While intervention group participants did reduce their overall antihypertensive medication pill burden at the 3 months compared to baseline, this was an exploratory outcome only and therefore there is no conclusive evidence to support the effect of the ENTICE-CKD program on blood pressure control in people with CKD.

Extended contact was effective at sustaining between-group 6 month changes for the increase in proportion of calories consumed from the core food groups (compared to baseline). Using extended contact to support sustainable behaviour change is central for effective dietary and lifestyle interventions and may delay intervention decay. However, no other changes in dietary intake or clinical parameters were sustained compared to the control group. Although there were no changes in clinical outcomes in the control group whilst receiving non-tailored, education-only text messages (from 3 to 6 months), they did improve the proportion of calories consumed from the core food groups they consumed. The fact that there was no between group differences at 6 months may be due to the study being underpowered, an active intervention commencing in the control, or the lack of effectiveness of tailored text messages to sustain dietary and clinical changes post intensive coaching, or both. Therefore, extended contact to improve CKD outcomes and delay intervention decay compared to both usual care and non-tailored education-only text messages requires further research in adequately powered trials.

This study has important limitations to consider. First, the ENTICE-CKD study was primarily designed to test the feasibility of the ENTICE-CKD program (as reported in Chapter 7). As such, many of the clinical outcomes were secondary or exploratory outcomes to generate hypotheses for future studies. Therefore, there is the chance of a type I error given the ENTICE-CKD intervention may be underpowered to detect changes the diet quality outcomes. Second, the ARFS as a measure of diet quality has never been validated in CKD. Furthermore, this is the only diet quality metric which does not associate to any renal outcomes in the literature, in comparison to the Alternate Healthy Eating Index, the Healthy Eating Index, the Mediterranean Diet Score, and the DASH pattern.[39] Therefore, there is a possibility of a type II error, and that the ARFS is not a suitable tool to assess dietary quality in people with CKD, and a more reliable tool should be considered in adequately powered future trails. Third, reliable comparisons to usual care can only be drawn at 3 months, as our wait-listed control participants started an active intervention from 3 to 6 months. It is therefore unclear whether a longer term, lower intensity intervention, such as the non-tailored education-only text messages may lead to similar results as observed in the tailored intervention over 6 months. Fourth, we measured clinic blood pressure, as a pragmatic measure to align with usual care practice. However, 24-hour ambulatory blood pressure is the gold standard for blood pressure measurement as it enhances precision, elimination of observer bias, and prevents the problematic 'white coat' hypertension. Finally, as is common for most dietary intervention trials, the majority of recruited participants were following a healthy diet already, which might signify a healthy volunteer bias.

In conclusion, 3 months of telephone coaching improved important components of diet quality for people with CKD, and reduced body weight compared to usual care. Extended contact through tailored text messages sustained some (but not all) aspects of improvements in diet quality compared to the control. Non-tailored education-only text messages did improve some components of diet quality from baseline following a 3 month intervention in the control group, but no clinical parameters were significantly changed at any time point.

Future trials which are adequately powered are needed to examine the long-term effect of a telehealth-delivered dietary intervention patient-centred quality of life, and renal and cardiovascular outcomes.

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8.8 Author contributions

JTK wrote the first draft of the manuscript and takes responsibility for the integrity of the data. JTK, KC, DJ, TH, DR, MR, JC, AT and SP assisted in the conceptualization of the trial design. JTK & MC designed the intervention materials and were responsible for the management of the trial at their respective sites. JK and RK provided recruitment logistic expertise and revised drafts of the manuscript. All authors contributed to revisions of the manuscript and approved the final version for submission.

8.9 Data sharing

The authors have made no plan to make the data of this pilot trial publicly available.

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Chapter 9 - Overall Discussion and Future Directions

The aim of this thesis was to develop and test the feasibility and acceptability of a patient-centred telehealth program for the dietary management of CKD. The preceding chapters detail individual studies which each make important and unique contributions to the evidence-base for renal nutrition and wider dietetic practice. Each of these chapters outline the successful conceptualisation, formative research, pre-testing, pilot and evaluation of the ENTICE-CKD program (see Table 9-1) (Whittaker et al., 2012). The framework followed in this thesis enabled the illustration of the key gaps in the literature for future research and the successful pilot of a randomised controlled trial. Collectively, the results of this thesis add important and novel contributions to the renal nutrition body of evidence and can inform future studies to develop and assess a telehealth-delivered dietary program in chronic disease populations.

Table 9-1: Summary of the key findings illustrated using the framework for developing telehealth programs

Development phase	Chapter	Key findings
Conceptualization	• **Chapter 2:** Literature review • **Chapter 3:** Scoped narrative review • **Chapter 4:** Systematic review of cohort studies	• **Key Finding:** A healthy dietary pattern may be associated with lower risk of all-cause mortality in established CKD populations • ***Gap remaining:*** *Not enough studies to determine associations to ESKD* • ***Gap remaining:*** *No standardised dietary pattern used in the literature - characteristics similar to recommendations in dietary guidelines* • ***Gap remaining:*** *No evidence to show how these interventions can be effectively delivered*
	• **Chapter 5:** Systematic review of telehealth interventions	• **Key Finding:** Telehealth-delivered dietary interventions are effective at improving diet quality and fruit/vegetable intake in chronic disease • **Key Finding:** Telehealth-delivered dietary interventions are effective at reducing dietary sodium intake, blood pressure and lipid profiles • **Key Finding:** Telephone coaching is the common telehealth-delivered dietary intervention in the literature, followed by mobile phone interventions • ***Gap remaining:*** *No telehealth-delivered dietary intervention conducted in pre-dialysis CKD*

Development phase	Chapter	Key findings
Formative research	• **Chapter 6:** Focus groups • **Appendix C:** Cross-sectional survey (not a primary publication of this thesis)	• **Key Finding:** People with CKD experience many barriers to implementing their diet recommendations; themes were patient-centred (fostering ownership and threats and ambiguities of risk) and healthcare specific (exasperating stagnancy and motivators and positive learning instruction) • **Key Finding:** People with CKD are open to using simple telehealth methods, such as the telephone and mobile phone, as long as patient-clinician relationships are maintained • ***Gap remaining:*** *Generalisability of findings to other CKD populations is unknown*
Pre-testing	• 'Beta-testing' the developed telehealth program • **Appendix D:** Quality testing	• Obtained feedback on intervention materials from people with CKD and expert clinicians (face validity) • Included people with CKD, nephrologists and academics
Randomised Controlled Trial	• **Chapter 7:** Feasibility and acceptability of a telehealth-delivered dietary intervention	• **Key Finding:** The ENTICE-CKD program was feasible and acceptable to participants with stage 3-4 CKD • ***Gap remaining:*** *The wider uptake of the intervention into clinical practice is unknown*
	• **Chapter 8:** Effectiveness of a telehealth-delivered dietary intervention	• **Key Finding:** The ENTICE-CKD program improved important aspects of diet quality (proportion of calories from core food groups, vegetable serves and fibre) • **Key Finding:** The ENTICE-CKD program reduced body weight and waist circumference • ***Gap remaining:*** *Lacking adequate powered trials to determine effectiveness*

Development phase	Chapter	Key findings
Qualitative research (interviews)	• **Appendix B:** Follow-up interviews with the ENTICE-CKD participants	• **Key finding:** The ENTICE-CKD program was acceptable in the stage 3-4 CKD population • **Key finding:** Positive experiences and overall acceptance of the fortnightly phone calls, tailored text messages and hardcopy workbook. • **Key finding:** Participants valued the relationship built with their coach over 12-weeks of contact because it increased their trust and confidence to discuss diet-disease mechanisms, goals, motivators, challenges and fears • ***Gap in the literature:*** *Selection bias. Those that did not participate in the ENTICE-CKD program may not have because of an aversion to using telehealth. Understanding how to ENTICE-CKD program would work in clinical practice is therefore unknown*

9.1 Conceptualisation

9.1.1 Dietary approaches

Chapter 3 was a narrative review which described the common challenges in implementing the renal nutrition evidence-based practice guidelines from both healthcare services and patients. The primary finding was that there was a paucity of evidence for the effectiveness of traditional renal nutrition approaches. Adopting a healthy plant-based dietary pattern may associate with reduced risks of important clinical outcomes in CKD and be easier for clinicians and patients to implement in clinical practice.

Chapter 3 hypothesised that it might be the collective effects of macro- and micro-nutrients consumed within the overall pattern of eating has one of the key mechanisms by which a healthy dietary pattern may improve clinical outcomes in CKD. For example, adopting a plant-based dietary pattern may reduce uremic toxins accumulation and promotes higher saccharolytic fermentation in the gut which produces short chain fatty acids which can improve lipid profiles and insulin sensitivity (Rossi, Johnson, & Campbell, 2015). Protein from soy reduce serum creatinine and C-reactive protein (Jing & Wei-Jie, 2016; Xu et al., 2015; Zhang, Liu, Su, & Tian, 2014), higher intake of fruit and vegetables reduce BP, metabolic acidosis and weight gain (Goraya, Simoni, Jo, & Wesson, 2013), low sodium diets reduce BP (McMahon et al., 2015), higher red and processed meat intake is associated with worse renal function (Lew et al., 2016) and higher fibre intake is associated with lower inflammation and all-cause mortality (Krishnamurthy et al., 2012). However, before a plant-based dietary pattern can feature in future evidence-based practice guidelines, large scale trials are needed to test their long-term effectiveness and safety.

Chapter 4 was a systematic review of observational cohort studies which aimed to evaluate the association between dietary patterns and all-cause mortality or ESKD among adults with CKD, giving further evidence to the theories discussed in Chapter 3. The primary finding was that from all the scientific literature available from large cohort studies, a healthy plant-based dietary pattern was consistently associated with a 35% reduced risk of mortality in CKD. While there was no standardised dietary pattern per se, there were consistent characteristics of dietary patterns promoting higher intake of healthy nutrients and/or food groups, that when consumed as part of an overall pattern, appeared to reduce the risk of all-cause mortality.

Chapter 4 concluded that clinicians could consider using a healthy dietary pattern as their intervention of choice with low risk CKD patients. However, the question remained about how people with CKD can best be supported in achieving a healthy dietary pattern. This healthy dietary pattern could be considered keeping with the dietary advice given in healthy eating guidelines to the general population (Chan, Kelly, & Tapsell, 2017; National Health and Medical Research Council, 2013), and may give rationale to public health strategies for both primary and secondary CKD prevention. Unfortunately, no cohort studies were identified within the search date of this review which limited the generalisation of the findings to the Australian context.

However, the candidate as a member of a larger research team recently completed a cohort study in stage 3-4 CKD participants in Australia (Appendix F) (Wai, Kelly, Johnson, & Campbell, 2016b). In this small (n=145) Australian cohort, a similar dietary pattern, predominantly higher in fruit and vegetables was associated with a 35% reduced risk of a composite outcome, mortality, ESKD and/or doubling of serum creatinine. This finding is in-line with the primary meta-analysis of international participant datasets, supporting the robustness of the finding and its generalisability to the Australian CKD population.

9.1.2 Delivery methods for complex dietary interventions

Chapter 5 was a systematic review which aimed to determine if alternate delivery methods (of dietary education), specifically telehealth methods, were effective at facilitating dietary change toward a ‘healthy dietary pattern’ in chronic disease. The primary finding was that telehealth methods are effective at improving diet quality and adherence scores, fruit and vegetable intake, and reducing dietary sodium intake. Furthermore, telehealth-delivered dietary interventions also led to reduced BP, lipid profiles and waist circumference outcomes.

The mechanism by which telehealth appears to improve outcomes may be through regular and repeated contact with participants. In a sub-group analysis, fruit and vegetable servings per day was greater in interventions providing weekly contact (1.32 serves/day [CI: 0.38, 2.26]), compared to interventions of monthly contacts or less (0.27 serves/day [CI: 0.02, 0.52]) (Kelly, Reidlinger, Hoffmann, & Campbell, 2016). Telephone and mobile phone interventions lend themselves to deliver regular contacts for dietary education. As over 68% of the interventions in Chapter 5 utilised either telephones or mobile phones, these are likely the telehealth modalities that people with chronic diseases feel most comfortable with due to having greater confidence in their use and because they are inexpensive, simple to use and facilitate regular and repeated contacts (Salisbury et al., 2015). The findings from Chapter 5 can be used to inform future policy and telehealth intervention development in chronic disease models of care.

This systematic review identified no dietary telehealth trials conducted in CKD populations. Before a telehealth trial could be designed for this population, adequate patient engagement was needed to complement the evidence synthesis of Chapters 4 and 5, to specifically ensure: a) telehealth is an acceptable addition to usual care in CKD; and b) it would assist people with CKD overcome their everyday dietary challenges and fit within a patient-centred model.

9.2 Formative Research to inform intervention development

Chapter 6 was a focus group study which aimed to explore the perspectives of people with stage 3-4 CKD about their dietary challenges and the potential to use telehealth. The primary finding of this study was that people with CKD experience a myriad of difficulties which challenge their adherence to dietary recommendations and telehealth was considered an acceptable option to assist with dietary self-management. Specifically, participants felt dietary advice was stagnant and they were confused with an ambiguous food supply that they found challenging to navigate. Furthermore, people wanted a preventative and supportive approach to diet in CKD and that the success of any telehealth intervention relied on it being as a complement to their usual care and patient-centred. The findings of Chapter 6 are in support of previous studies. A systematic review of qualitative studies highlights the complexity that people with CKD view dietary recommendations (Palmer et al., 2014). Participants in this study reported better self-management when taking responsibility for their treatment, however wanted regular contacts with health professionals to feel supported and empowered to make further dietary changes (Palmer et al., 2014). Despite this, people with CKD do not commonly receive co-ordinated and multidisciplinary care (Bear & Stockie, 2014; Lo et al., 2016). Participants in the focus group study reported in Chapter 6 felt that renal services were inflexible and out-dated, which ultimately led to a patronising patient experience, not aligned to patient-centred care.

Although participants in the focus group study wanted a preventative and co-ordinated approach to their disease progression, it is acknowledged that this may not be feasible in the current healthcare system. Specifically, tertiary hospitals in Queensland have insufficient resources to effectively assess and review pre-dialysis patients (Campbell & Murray, 2013) and international studies have shown that dietitians commonly do not have the time to carry out standard nutrition care for people with CKD (Hand, Steiber, & Burrowes, 2013).

The results from Chapter 6 show that telehealth was viewed as an acceptable low-cost option to compliment participants' current care, particularly in supporting positive dietary changes. While telehealth itself was not a 'theme' which emerged in the inductive analysis, each of the five themes had important sub-themes related to telehealth, which participants viewed to facilitate (or hinder) achieving their dietary recommendations. For example, 'seeking kidney diet information', 'making reminders' and 'tracking progress against targets' were all subthemes within the overarching theme of 'Fostering Ownership'. Simple-to-use telehealth modalities can facilitate these patient values for enacting dietary change. Furthermore, under the central theme 'Supporting and Sustaining Change', three of the five subthemes ('receiving regular feedback', 'incremental and comprehendible modification', and 'flexibility in monitoring schedule') were identified to be possibly achieved by using telehealth methods (Tuot & Boulware, 2017).

Chapter 6 concluded that people with CKD desire a preventative approach to CKD progression however, are stymied by restriction-focused dietary advice and a lack of dietetic service provision in the earlier stages of their disease. Telehealth methods such as the telephone and text messaging were viewed as acceptable over other telehealth options and could assist with dietary self-management. These views and experiences were used to inform the development of a new telehealth program, specifically for the dietary self-management of CKD in Queensland (titled ENTICE-CKD).

9.3 Pre-testing

9.3.1 Feasibility and acceptability of the intervention

Chapter 7 reports on the process evaluation of the pilot telehealth program, ENTICE-CKD. The aim of Chapter 7 was to assess the feasibility and acceptability of telehealth-delivered dietary coaching to support the improvement of dietary quality in stage 3-4 CKD over a six-month period. The primary finding was that the ENTICE-CKD program was a feasible intervention which was delivered according to protocol and enabled participant adherence. The ENTICE-CKD study successfully recruited 80 participants, of which 95% remained in the study over its 6 month duration. The tailored telephone calls and text messages were acceptable to participants in this pilot, particularly for encouraging and motivating healthy dietary changes. In contrast, the acceptability varied for those in the non-tailored education-only text message (control) group, who received a 3 month text message intervention only, with no tailoring to participant's goals or prompts to encourage self-monitoring of those goals.

The feasibility and acceptability of the ENTICE-CKD program demonstrated that dietary coaching through phone-based and text message platforms may provide an alternate strategy for providing the frequent and structured contact that is needed to support the complex dietary changes in CKD. However, it is important to note that the results of the ENTICE-CKD process evaluation specifically relate to the 35% of people who agreed to participate in the study and the wider feasibility and acceptability in people who are less motivated to participate is unknown. It is a recognised limitation in conducting dietary trials in populations where non-adherence is well-characterised, that people who participate in dietary intervention studies are commonly motivated to make dietary change (Crichton et al., 2012; MacNeill, Foley, Quirk, & McCambridge, 2016). In CKD populations specifically, adherence to common dietary approaches is as low as 20% for low sodium diets (McMahon, Campbell, Mudge, & Bauer, 2012) and as low as 15% for low protein diets (Woodrow, 2018). This illustrates the importance for future research to determine the feasibility of the ENTICE-CKD program in wider clinical practice and look to potential ways to engage with people who are less motivated to change their diet and lifestyle.

Extensive process evaluation is important for replication and future intervention development. Unfortunately, the long-term maintenance and effectiveness of the ENTICE-CKD program is unclear from the process evaluation reported in Chapter 7. Maintenance of behaviour change would require longer-term follow up with participants than was feasible within this PhD candidature. Some evidence of maintenance can be observed in the sustained levels of self-monitoring evident from the second call through to the final coaching call in the ENTICE-CKD study. However, future research is needed to evaluate more systematic data regarding the programs maintenance to enable reliable conclusions. To ensure the long-term maintenance at the individual and organisational level, there is opportunity to extend the intervention to incorporate the use of social networks and a multi-disciplinary team to build self-efficacy in other aspects of participants' lifestyle. This was also an important consideration raised in participant interviews (post-intervention), as a key component to future self-efficacy which was not addressed by the ENTICE-CKD program.

9.3.2 Effectiveness of the intervention

Chapter 8 aimed to determine the safety and potential effectiveness of the ENTICE-CKD telehealth-delivered intervention for improving diet quality and clinical parameters in stage 3-4 CKD. The primary finding was that participants in the intensive coaching arm of the study significantly improved important components of dietary quality specific to CKD including an increase in the proportion of calories from core (non-discretionary) foods, total vegetable serves per day and total fibre intake.

Secondary outcomes, including body weight and waist circumference were significantly improved in the intensive coaching arm compared to the control, whereas BP did not significantly decrease at any time point. Some, but not all dietary changes were sustained following 3 months of extended contact through text message reminders. The control group showed modest changes in aspects of dietary quality at 6 months, once they started to receive non-tailored education-only text messages. However, there were no observed changes in any clinical parameters in the control group throughout the 6 month study duration.

No adverse events related to the intervention or safety concerns were reported throughout the trial. The Australia Dietary Guidelines may therefore represent a 'healthy' dietary pattern which can safely emphasise fresh fruit, vegetables and wholegrain consumption and improve overall diet quality in CKD. Caution has long been advised against encouraging higher intakes of fruit, vegetables and wholegrains in CKD, as such recommendations are inherently higher in potassium and phosphate and therefore may place people at risk of hyperkalaemia or hyperphosphatemia. The results of the ENTICE-CKD study are in support of previous commentary which has urged clinicians to consider liberalising the renal diet to improve diet quality (Biruete, Jeong, Barnes, & Wilund, 2017), now showing this to be a clinically safe intervention.

The overall diet quality measure used in the trial was the Australian Recommended Food Score (ARFS), which is validated against the Recommended Food Score (Collins et al., 2015) and did not significantly change in either group. The choice was made to utilise an Australian FFQ which was validated in the Australian adult population (non-CKD) because this method fitted the pragmatic design of the study and as it generated instant reports which the dietitian coaches could utilise in their coaching. However, the ARFS as a diet quality indicator is neither validated to measure to assess diet quality in CKD, nor does it associate with meaningful renal outcomes (Smyth et al., 2016). This does not explain why the ENTICE-CKD trial did not observe a change in ARFS, despite other changes in dietary intake. However, it does question the relevance of this tool for future CKD studies. A future study should consider using an FFQ system which easily enables the calculation of diet quality indices such as the Alternative Health Eating Index, the DASH diet score or Mediterranean Diet Score. Specifically, the Australian FFQ utilised in this pilot did not calculate food group servings of meat/alternatives, dairy or breads/cereals, as whole serves per day. It may be possible for future research to calculate a diet quality index for the ENTICE-CKD study based on published scoring systems for the Alternate Healthy Eating Index (Sotos-Prieto et al., 2017), the Mediterranean Diet Score (Trichopoulou, Costacou, Bamia, & Trichopoulos, 2003), and the DASH diet score (Fung et al., 2008), however it was beyond the scope of this PhD candidature.

9.4 Qualitative follow-up

The qualitative follow-up of participants that participated in the ENTICE-CKD program is important for informing future effectiveness trials, and its wider implementation into clinical practice. People who undertook the first phase of the telehealth intervention were interviewed, and results analysed using content analysis (for acceptability and feasibility [Chapter 7]) and thematic analysis (of experiences with the telehealth coaching program [Appendix B]). These interviews highlighted the acceptability and feasibility of the intervention, whereby participants preferred the frequent contact of the telephone calls and text messages to reinforce dietary changes. Participants also expressed that the regular contacts fostered a supportive relationship between participant and coach, which was viewed to allow for greater social accountability and progressive dietary change.

Overall, the results of the qualitative follow-up showed support for the acceptability of the ENTICE-CKD program, however this only relates to the people who participated in this pilot. Further qualitative research is needed to understand the significant proportion of people with CKD who did not wish to participate in the ENTICE-CKD program. This could be used to adapt recruitment and retention strategies and assist the wider translation into clinical practice.

9.5 Is a telehealth-delivered coaching program translatable into practice?

Successful dissemination and implementation of telephone coaching programs have been achieved in the general (non-CKD) setting in Australia. Dissemination of the ‘Optimal Health Program’ in the South-East region of Queensland provides evidence that this type of service can be successfully implemented in the chronic disease community of Queensland. The Optimal Health Program was evaluated predominantly using the RE-AIM framework (Glasgow, Vogt, & Boles, 1999) and observed significant reductions in weight and waist circumference over the 12-month evaluation period (Goode, Reeves, Owen, & Eakin, 2013). Similarly the implementation of the ‘Get Healthy’ free telephone coaching program in New South Wales (and now available in Queensland) (NSW Government, 2018; Queensland Government, 2018) showed a 35% uptake in New South Wales and highlights key barriers to implementation relating mostly to not offering adequate flexibility in the program (Khanal et al., 2016). This program was evaluated using the process of implementation and impact evaluation framework outlined by Bauman & Nutbeam (Bauman & Nutbeam, 2013).

Understanding what elements of implementation interventions are effective is central to successfully translating the ENTICE-CKD program into practice. Essential features of a successful implementation intervention have been identified in a review of primary care CKD interventions (Tsang, Blakeman, Hegarty, Humphreys, & Harvey, 2016). Primary care interventions should address CKD in the context of cardiovascular health or diabetes, as this facilitates a more holistic understanding of CKD and is thought to better engage people to participate in an intervention. Implementation interventions should also build on existing programs or practices which enable them to be more efficiently integrated into primary care. This work emphasises the importance of an implementation program being patient-centred. Specifically, this includes giving participants ownership in interventions, individualising and tailoring interventions to suit individual needs and fostering collaborations between participants, doctors and allied health professionals (Tsang et al., 2016).

To facilitate translation of the ENTICE-CKD program into practice, there are implementation frameworks which would be appropriate to follow (Nilsen, 2015) (discussed later in Section 9.8 - Future directions: Recommendation 5). The implementation of the ENTICE-CKD program would likely be achieved by following the Knowledge-to-Action Framework (Graham et al., 2006). This thesis has completed the Knowledge-Creation phase (Graham et al., 2006) specifically through the completion of scoping reviews (Chapter 2 and 3), systematic reviews (Chapters 4 and 5) and stakeholder engagement (Chapter 6 and Appendix C). It is prudent to note that although the ENTICE-CKD program has demonstrated feasibility, acceptability, safety, and potential effectiveness for exploratory clinical parameters, the long-term effectiveness, maintenance and feasibility of the wider implementation of the ENTICE-CKD program is an unanswered question for this thesis. Implementation of the Action-phase of the Knowledge-to-Action Framework (Graham et al., 2006) will require future research to determine the effectiveness, maintenance (both at the individual and organisational level) and uptake into clinical practice. These implications have been used to formulate specific recommendations (discussed further in Section 9.8 - Future directions and recommendations).

9.6 Implications for implementing a chronic disease telehealth program in Australia

As part of step 1 in the Knowledge-to-Action Framework, it is important to identify problems and adapt the knowledge creation to a local context (Graham et al., 2006). The most important context to consider is the healthcare setting that the ENTICE-CKD program best fits.

The Australian health care system relies on a mixture of services funded by government (both State and Commonwealth) and non-government (private health insurance) agencies. An important limitation to the delivery of telehealth services and uptake into usual dietetic care is a lack of meaningful reimbursement under Medicare (i.e. the Australian public health system) and private health insurers. This is an issue facing health care systems internationally (Kruse et al., 2018; Raven & Bywood, 2013; Schwamm et al., 2016).

9.6.1 Medicare

In Australia, Medicare provides rebates for one-on-one consultation with a qualified dietitian, which must only be conducted face-to-face. This means online, and other telehealth modalities are either utilised at the expense of the clinician, or the costs are passed onto the patient, both of whom are unable to claim an eligible rebate.

The Medicare Benefits Schedule (MBS) currently recognises videoconferencing as the sole telehealth modality eligible for rebate. Medicare rebates are available for these services between medical specialists and patients, where an audio-visual link is maintained for the duration of the consultation (Department of Health, 2018). In the 2017-2018 Australian Federal budget, some allied health professional services were added to the MBS under the Better Access Initiative (Department of Health, 2018). These ‘Better Access’ telehealth services can be delivered by clinical psychologists, registered psychologists, occupational therapists and social workers (Department of Health, 2018). However, dietary and exercise physiology interventions delivered by dietitians or exercise physiologists are not part of this initiative and therefore people with chronic diseases requiring lifestyle interventions are not able to access telehealth services from these allied health professionals easily.

9.6.2 Private health insurance

Private health insurance (additional health cover to that provided under Medicare) is optional, to reimburse all or part of the cost of hospital and additional health services. The Australian Bureau of Statistics estimates that 55% of Australians had private health insurance for ‘extras’ cover (which provides rebates for non-hospital services including for dietitian services in some circumstances), and 47% had hospital cover in 2016 (Australian Prudential Regulation Authority (APRA), 2017). In 2007, changes to the Private Health Insurance Act included extended benefits to Broader Health Cover (BHC) which the majority of private health funds offer in today’s market. BHC enables private health insurers to offer their members with a chronic disease access to claimable programs (some of which can be telehealth) which are designed to prevent health complications related to that disease (Biggs, 2013).

Some private health insurers offer some form of telehealth services as part of BHC in Australia. For example, Medibank Private Health has an initiative for their members, including a team of allied health professionals which include exercise physiologists, dietitians and nurses (Medibank Health Solutions, 2018). The initiative is telephone-based coaching to control risk factors known to lead to hospital admissions and other associated health benefit claims (Medibank Health Solutions, 2018). Another health insurance product, provided through AHM insurance offer a similar ‘Total Health Program’ to their members (Medibank Health Solutions, 2018). The Hospitals Contribution Fund of Australia (HCF) offer ‘Healthy

Weight for Life', however only for those with appropriate level of cover and it specifically targets weight loss, where there is no other risk factors (Health Comes First (HCF), 2018). HCF also offer all their members access to 'My Health Guardian', an online system with tools to help with diet, health and fitness (Health Comes First (HCM), N.D). With private health insurers more inclined to offer telehealth services in chronic disease than government funded health services, the ENTICE-CKD program may have wider uptake if it is offered through private agencies.

In a 2013 video consultation policy review, the evidence-base for the effectiveness of all allied health professionals using video conferencing was summarised (Raven & Bywood, 2013). The evidence for dietetic services specifically was favourable, however primarily based on low-quality evidence, conducted in small sample size studies and reported mostly in feasibility studies which were not designed to establish long-term effectiveness (Raven & Bywood, 2013). The evidence base was similar in quality and findings for all allied health disciplines. With the added evidence from the telehealth-delivered dietary interventions systematic review (Chapter 5), future research should look to determine whether these services are cost-effective and have feasibility for wider uptake into clinical practice. This future work fits into the 'assess barriers/facilitators to knowledge use' in the Action-phase of the Knowledge-to-Action framework (Graham et al., 2006) (discussed further in Section 9.8 - Future directions and recommendations).

In summary, despite recent changes in the Australian healthcare system, there are many limitations to the implementation of the ENTICE-CKD program into clinical practice. However, with future research this thesis summarises and reports evidence which can be used to inform policy change and a future implementation study. Future research and any future implementation study should be conducted in-line with the Knowledge-to-Action Framework (Graham et al., 2006).

9.7 Strengths and limitations of this thesis

This thesis reports on the first randomised controlled trial to examine the feasibility and acceptability of a telehealth program to improve dietary quality in people with CKD. There are several important strengths to note. First, this thesis demonstrates that a robust process was used to develop the telehealth program including two comprehensive systematic reviews, one which examined all trial literature on the dietary delivery method (telehealth) in all diet-related chronic diseases and one examining the associations of the planned dietary approaches (healthy dietary pattern) in CKD. Second, this thesis describes extensive CKD patient-engagement co-creation approach used to develop and pilot the telehealth-delivered intervention. This includes a technology-use survey (Appendix C) and a qualitative study (Chapter 6) to inform the intervention development and address the concerns that people with CKD have about achieving their dietary recommendations. Patient feedback on the intervention materials was also sought, prior to finalising materials for the intervention study (example in Appendix D). Further patient-engagement activities were also conducted following the ENTICE-CKD intervention, through one-on-one interviews and surveying the utility and acceptability. The co-creation of the ENTICE-CKD program with patients may be a key reason for the successful recruitment and retention of participants in the trial (Chapter 7). Finally, a pragmatic intervention design of telephone coaching and text messages in the ENTICE-CKD study was used to achieve the implementation of this intervention and enable a future large-scale effectiveness study.

Despite these key strengths, there are important limitations to consider. Each of the projects contained in this thesis have limitations which have been summarised in their corresponding chapters. A summary of the limitations of each chapter is provided in Table 9-2.

Table 9-2: Summary of the key limitations of each of the studies included in this thesis.

Chapter	Summary of key limitations
3 (Narrative Review)	Did not use a systematic search. Inherent biases of narrative reviews which can relate to the researchers' knowledge of the subject field, and selection of citations which supports the topic of the review.
4 (Systematic Review of Cohort Studies in CKD)	Non- standardised 'healthy dietary patterns'. Dietary assessment based on self-recalls via differing methods. The cohorts had participants with a range of different kidney functions. Limited generalisability to other global regions (other than United States and Sweden). Limited ESKD events, so no reliable conclusion on an association can be drawn. Unable to assess for evidence of publication bias. All results were based on non-randomised data.

Chapter	Summary of key limitations
5 (Systematic Review of Telehealth Interventions in Chronic Disease)	Diet recommendations were only components of multifactorial lifestyle interventions in 22 of the 25 included studies. Limiting generalisability for other telehealth modalities other than the telephone. Poor intervention reporting in included studies. Unable to assess important clinical endpoints, such as mortality and hospitalisations.
6 (Qualitative study exploring patient experiences with dietary recommendations and perceptions of telehealth)	Generalisability of themes to other populations with CKD is unknown. Did not achieve a sample reflective of the current CKD demographic in Australia.
7 (Feasibility and acceptability study – the ENTICE-CKD randomised controlled trial)	The feasibility and acceptability results only relate to the enrolled participants. Limited generalisability to people with lower health literacy due to only 10% of participants with low health literacy recruited. Participant adherence to the intervention captured using non-validated surveys. Non-tailored education-only (control) group participants were not interviewed post-intervention.
8 (Effectiveness of the ENTICE-CKD randomised controlled trial)	Underpowered to detect change in effectiveness outcomes. Reliable comparisons to usual care can only be drawn at 3 months, because control group commence an active intervention from month 3-6. Unable to determine whether a longer term non-tailored education-only text message intervention would lead to similar results as observed in the tailored intervention over 6 months. Use of clinic blood pressure measurement and not the gold standard 24-hour ambulatory blood pressure monitoring. Potential volunteer bias: unable to determine the effects of the intervention on people with poor dietary quality and/or lower motivation to participants in dietary research trials.

9.8 Future directions and recommendations

The future recommendations arising from this body of work address the remaining gaps in the literature and key recommendations from individual chapters contained within this thesis. Each recommendation has been considered with what is needed to transition the ENTICE-

CKD program to the Action-phase in the Knowledge-to-Action Framework (Graham et al., 2006). These recommendations are discussed in detail below.

Recommendation 1: Conduct a large randomised controlled trial to determine the effectiveness of the ENTICE-CKD program over a longer period.

This thesis has shown the feasibility and acceptability of the ENITCE-CKD program. However, before the wider implementation could be considered, a large randomised controlled trial is needed to test the program's overall effectiveness for controlling BP and preserving renal function.

A future effectiveness trial should consider the following learnings from the pilot ENTICE-CKD trial:

1. Enhance the generalisability of the study sample by recruiting participants from primary care (including general practices) and public and private nephrology units.
2. Extend to at least a 12-month intervention period (6 month active intervention with 6 month extended contact), with an observational follow up for dietary behaviour at 24 months to evaluate the maintenance of behaviour change.
3. Modify the structure of coaching calls, which may include some tailoring based on participants' progress. All participants who completed call 1 went on to complete at least 4 calls in the ENTICE-CKD pilot. While reasons for missing the final two calls did vary, these calls were used for check-in and review of goals only. This could therefore be done at the participant's discretion and to give participants more flexibility, which was a key learning from this thesis - that people with CKD want flexibility in their monitoring schedule.
4. Trial the addition of education and support for general lifestyle change (including exercise and medication adherence, in addition to dietary education) as part of the intervention.
5. Enhance the accuracy of outcome measures. This would include physical activity, 24-hour ambulatory BP and medication adherence. Furthermore, capture dietary intake data in such a way that a diet quality index such as the Alternative Health Eating Index, can be applied to determine changes in diet quality in this population. This index has evidence associating it with all-cause mortality and renal end-points outcomes in the general population (Smyth et al., 2016; Sotos-Prieto et al., 2017).

6. Future interventions to be powered for 24-hour ambulatory BP and/or an eGFR drop of 30% from baseline (which is considered an important clinical end-point in CKD) (Levey et al., 2014).
7. Due to the unexpected large volume of over 1,000 ‘unrecognised’ text messages sent by participants - adapt the program to provide an automated response.

Recommendation 2: Investigate barriers to people with CKD participating in dietary trials and ways to encourage people who are not motivated to participate.

The ENTICE-CKD study had a 35% recruitment rate, which is a similar recruitment rate to other dietary trials in the literature. However, the potential for implementation of this program will be dependent on the program’s ability to engage people who are not already motivated to change their diet. To investigate this topic, the following could be considered:

1. Engage general practitioners, nephrologists and renal nurses and explore their expectations on dietary services provided to their patients. Specifically, there is a need to research general practitioners, nephrologists and renal nurse barriers to referral to dietary services and their expectations on outcomes. This could be done in a nation-wide cross-sectional survey, which could be administered through national bodies such as the Australasian Kidney Trial Network, and/or the Australia & New Zealand Society of Nephrology. This recommendation is based on findings from the qualitative data in ENTICE-CKD, where many participants reported that their motivation to participate had come at the suggestion of their nephrologist. Approximately 69% of nephrologists report hesitation in prescribing (either ‘never’ or ‘rarely’) low protein dietary advice and less than half would consult a dietitian if they chose to intervene (Kalantar-Zadeh et al., 2016). Therefore, conducting this work could help understand a strategy for better engaging the target population for future trials.
2. Collect and analyse qualitative data on reasons for non-participation in trials, consider inviting non-participants into a qualitative study to investigate reasons for non-participation in dietary trials. This work could be influential for the wider dietetic community to understand how services can best match patient priorities, and better address health inequities through strategies that target people with lower motivation to change their diets.

Recommendation 3: Conduct cost-effectiveness investigations for the ENTICE-CKD program.

One of the key barriers to the wider implementation of telehealth interventions is that evidence is lacking about its cost-effectiveness (Henderson et al., 2013). The evidence retrieved from the systematic review of telehealth interventions (Chapter 5) did not allow a cost-effectiveness summary analysis due to insufficient data. Conducting a cost-effectiveness analysis of a dietary program in chronic disease would assist policy makers in decision making about whether to fund such programs.

To conduct this type of analysis, data needs to be collected to evaluate the relative resource use and costs associated with both the telehealth intervention and the control intervention. This could be done as follows:

1. Consider keeping a record of start-up costs related to development and delivery of the intervention. Costs include programming of the software, technical and coach staffing, the telephone-delivered coaching (training, call duration, call attempts, phone call cost, text-messages, and overheads), the automated text-message system and software licences.
2. Capture downstream healthcare utilisation over the duration of the trial and follow-up using a patient-report calendar approach, including visits to any healthcare providers (e.g. general practitioner, specialist, and allied health) and visits to hospital or the emergency department (including linkage to diagnosis-reference groups).
3. Capture health utility which is evaluated using the measure 'Assessment of Quality of Life' questionnaire (AQoL-4D) (Hawthorne, Richardson, & Osborne, 1999), a validated instrument which was used in ENTICE-CKD study. The AQoL-4D can be used to estimate the health benefit of the intervention, an important measure to evaluate cost-effectiveness of this type of intervention.

Recommendation 4: Conduct a large prospective cohort study to examine the association of multiple dietary patterns and single nutrients (such as sodium and protein) with progression to ESKD in a cohort with established CKD.

More research is needed to understand the potential associations of dietary patterns and progression to ESKD. This thesis was unable to determine whether a healthy dietary pattern reduces the risk of ESKD (Chapter 4). End-stage kidney disease is a relatively rarer complication of CKD due to the competing risk of death (discussed in Chapter 2) and demonstrated by the event rate reported in Chapter 4 (3,983 events for mortality, 1,027 events for ESKD). Therefore, progression to ESKD needs to be captured in large databases including robust dietary data in the CKD population and long-term (>10 years) follow up. While the use of registry-based trials may help to ameliorate this challenge (Perkovic et al., 2017), a large prospective cohort study is a pragmatic study design which could capture this data.

Recommendation 5: Plan for the translation of the ENTICE-CKD program into practice using established implementation science frameworks as a guide.

The ENTICE-CKD program is feasible, acceptable, safe and may be effective at improving dietary quality in people with CKD. However, longer-term studies are needed to determine its clinical effectiveness and long-term maintenance before wider implementation is recommended. To facilitate the translation of telehealth initiatives, such as ENTICE-CKD into practice, the utilisation of implementation frameworks is encouraged (Nilsen, 2015). For example, by using the Knowledge-to-Action cycle (Graham et al., 2006), this thesis provides has started to inform the Knowledge Creation stage through its extensive systematic and scoping reviews (knowledge synthesis) and stakeholder engagement (knowledge inquiry). Moving into the 'Action cycle' of this framework provides practical guidance in the planning and execution of its implementation.

However, it is recognised that this thesis has simply shown a novel telehealth program to be feasible and acceptable, and the effectiveness results need to be evaluated in larger and longer-term studies. If the ENTICE-CKD program was to be implemented into practice, the following points should be considered:

1. Utilising existing telehealth models of care in chronic disease, to facilitate the translation into practice. This could include modelling successfully implemented telehealth programs, such as the 'Optimal Health Program' (Goode et al., 2013) and 'Get Healthy' (Khanal et al., 2016).
2. An implementation study should be based on the Action-phase in the Knowledge-to-Action framework (discussed above) to capture important process data which can determine the program's long-term feasibility in clinical practice.
3. This program could be tested in clinical practice using a community-based cluster randomised implementation trial (Puffer, Torgerson, & Watson, 2005). This would mean randomisation would be conducted at the recruiting organisation level, rather than the

individual level. This would be less resource intensive and still enable important comparisons of referral rates and clinical effectiveness

4. Under the current models of healthcare, private health insurance agencies may be more likely to adopt this program for wider chronic disease management (American Hospital Association, 2016).

9.9 Conclusions

The individual studies completed within this thesis were conducted with the overarching aim to develop and test the feasibility and acceptability of a patient-centred telehealth program for dietary self-management in people with CKD. Through two systematic reviews, this thesis has shown that healthy dietary patterns are associated with a reduced risk of death, are a possible dietary approach in CKD and that telehealth methods are effective in delivering dietary education in chronic disease. Using a qualitative design, this thesis utilised focus groups as a form of patient-engagement to collect patient-centred experiences with dietary recommendations and perceptions about using telehealth to support self-management. These three projects were collectively used to develop a patient-centred telehealth program (the ENTICE-CKD program) to improve diet quality in people with CKD. The ENTICE-CKD program was shown to be feasible and acceptable to people with CKD and was successfully delivered to protocol. The intensive coaching (intervention) group improved aspects of their diet quality and reduced their body weight and waist circumference. The non-tailored education-only text message (control) group participants observed some modest changes in components of diet quality but no significant changes in any clinical parameters. Collectively, the results of this thesis can be used to inform future public policy for the use of telehealth for dietary education in chronic disease management and a large-scale randomised controlled trial of the effectiveness of the ENTICE-CKD program in clinical practice.

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Appendices

Appendix A:	Manuscript (published): Systematic Review Protocol (complementary with Chapter 5)
Appendix B:	Manuscript (draft): Qualitative follow-up of experiences in the ENTICE-CKD program (draft manuscript; complementary with Chapter 7)
Appendix C:	Manuscript (published): Patient-engagement survey (complementary with Chapter 6)
Appendix D:	Example Consumer feedback on workbook for ENTICE-CKD program
Appendix E:	Manuscript (published): Protein and CKD progression (complementary with Chapter 3)
Appendix F:	Manuscript (published): CKD.QLD study (complementary with chapter 3)
Appendix G:	Chapter 4 search terms
Appendix H:	Manuscript (published): TIDieR reporting in telehealth-delivered dietary interventions (complementary with chapter 5)
Appendix I:	Chapter 6 focus group questions and vignettes
Appendix J:	ENTICE-CKD workbook given to the intervention and control groups
Appendix K:	Chapter 7 Utility and acceptability questionnaire
Appendix L:	Chapter 7 interview schedule for the semi-structured interviews

Appendix A: Systematic Review Protocol (complementary with Chapter 5)

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Systematic Reviews

PROTOCOL Open Access

Telehealth methods to deliver multifactorial dietary interventions in adults with chronic disease: a systematic review protocol

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Abstract

Background: The long-term management of chronic diseases requires adoption of complex dietary recommendations, which can be facilitated by regular coaching to support sustained behaviour change. Telehealth interventions can overcome patient-centred barriers to accessing face-to-face programs and provide feasible delivery methods, ubiquitous and accessible regardless of geographic location. The protocol for this systematic review explains the methods that will be utilised to answer the review question of whether telehealth interventions are effective at promoting change in dietary intake and improving diet quality in people with chronic disease.

Methods/design: A structured search of Medline, EMBASE, CINAHL, and PsychINFO, from their inception, will be conducted. We will consider randomised controlled trials which evaluate complex dietary interventions in adults with chronic disease. Studies must provide diet education in an intervention longer than 4 weeks in duration, and at least half of the intervention contact must be delivered via telehealth. Comparisons will be made against usual care or a non-telehealth intervention. The primary outcome of interest is dietary change with secondary outcomes relating to clinical markers pre-specified in the methodology. The process for selecting studies, extracting data, and resolving conflicts will follow a set protocol. Two authors will independently appraise the studies and extract the data, using specified methods. Meta-analyses will be conducted where appropriate, with parameters for determining statistical heterogeneity pre-specified. The GRADE tool will be used for determining the quality of evidence for analysed outcomes.

Discussion: To date, there has been a considerable variability in the strategies used to deliver dietary education, and the overall effectiveness of telehealth dietary interventions for facilitating dietary change has not been reviewed systematically in adults with chronic disease. A systematic synthesis of telehealth strategies will inform the development of evidence-based telehealth programs that can be tailored to deliver dietary interventions specific to chronic disease conditions.

Systematic review registration: PROSPERO CRD42015026398

Keywords: Telehealth, Dietary, Diet quality, Adults, Chronic disease, Behaviour change, Lifestyle change, Technology

Background

Non-pharmacological treatment methods are commonly used for people with chronic diseases [1], and many of these require lifetime adherence to dietary recommendations. Telehealth technologies can provide education and self-management support to facilitate and sustain lifestyle changes. Such interventions (which include telephone coaching, the Internet, mobile phone applications) could have advantages over traditional face-to-face models of care [2], and utilisation of them may assist with achieving dietary behaviour change [2–4].

Description of the condition

Chronic disease is the leading cause of ill health, accounting for 68 % of all deaths worldwide [5], in some countries contributing to over 90 % of all deaths [6]. Chronic diseases are those with multifactorial aetiologies, and once diagnosed, are with the individual for life without a specific cure. Many chronic diseases are

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diet-related, specifically obesity, heart disease, diabetes, hypertension, stroke, and kidney disease as previously defined in a systematic review [7]. These pose a significant challenge to the health system, in terms of costs and cause of death and disability, which tends to be related to cardiovascular disease (CVD) as either the primary or co-morbid condition [8]. Self-management and the adoption of a healthy lifestyle, such as through diet, physical activity, and other health-related behaviours (e.g. smoking cessation), are considered essential for the management of these diet-related chronic diseases [9, 10].

Telephone-delivered interventions for smoking cessation [11] show improvements in quit rates, and physical activity [2] interventions delivered at least 50 % by telephone show increases in all measures of physical activity, which is also sustained following the conclusion of interventions. However, the findings from studies aimed at increasing adherence to specific dietary recommendations in chronic disease lack consistent findings in controlled studies [12].

Description of the intervention

According to the World Health Organisation [13], the definition of telehealth is encompassed by the definition of telemedicine, which refers to the delivery of health-care services at a distance, using information and communication technologies to exchange health information. A distinguishing characteristic of telemedicine is that it is restricted to healthcare delivery by physicians only, whereas telehealth services are provided by any health professional and can include either synchronous (i.e. same time, different location) and asynchronous (i.e. different time, different location) patient education, counselling, and remote monitoring [13]. A telehealth lifestyle intervention may involve the provision of lifestyle education or advice to an individual or group of individuals remotely via the telephone [14], computer, and the Internet [15–17], videos [18], email [19], and/or mobile phone applications including text, photo messages (short message service (SMS), or multimedia message service (MMS)) [20, 21].

How the intervention might work

For lifestyle interventions to achieve long-term behaviour change, an intensive approach which involves frequent engagement and ongoing monitoring is recommended [1, 9, 12]. This is particularly true for changes that require the long-term maintenance of dietary strategies, which require a high degree of self-management and are notorious for poor compliance and high participant burden [22]. To improve compliance, regular contact with treating clinicians and an emphasis on self-monitoring have been suggested as central to the success of a complex dietary intervention [23, 24]. Interventions which use telehealth strategies offer expedient and feasible ways to provide the recommended support to individuals to facilitate behaviour change. For example, individuals who have limited time to attend face-to-face education could access an education program from the comfort of their own home at a time of their choosing [25]. An advantage of telehealth interventions is that educational content can be provided live (synchronous) between patient and health professional, or through text messages, emails, and Internet outlets (asynchronous and mobile health), thus overcoming some of the common barriers to face-to-face care.

Why it is important to do this review

Technology to deliver health-related interventions have been used for over 25 years with mixed results, ranging from no effect at all to significant improvements in health outcomes [26]. Despite a range of telehealth methods for the management of chronic disease [2, 8, 27–31], as well as CVD risk behaviours [8], the effectiveness of telehealth interventions to facilitate dietary change has not been systematically synthesised. A recent systematic review demonstrated that telephone coaching is feasible for establishing effective behavioural change for physical activity and/or dietary interventions [2]. However, only two dietary studies met the inclusion criteria for this review, and studies were not specific to chronic disease. A recent systematic review demonstrated that telephone coaching is feasible for establishing effective behavioural change for physical activity and/or dietary interventions [2]. However, only two dietary studies met the inclusion criteria for this review, and studies were not specific to chronic disease. Another (Cochrane) review investigated the effectiveness of different interventions, in promoting adherence to dietary recommendations [12]. However in this review, although some included studies may have used telehealth as a component of the intervention, they did not evaluate the effectiveness of telehealth interventions specifically and did not compare to usual care (defined in its broadest sense, and which could include non-telehealth-delivered dietary advice from a health professional or no dietary education at all).

Despite a number of previous systematic reviews covering different combinations of telehealth and/or population groups (healthy and chronic disease), these reviews have not specifically evaluated interventions that attempt to change dietary patterns (i.e. multiple food groups or nutrients) which represent the dietary management of chronic disease [32].

Recent technology-based trials educating to the dietary guidelines (via the telephone) [14] and the DASH diet (via the Internet) [33] showed significant improvements in measures of dietary intake (such as fruit and vegetable consumption) for strategies using technology compared to those using more traditional strategies. Such evidence is promising for future healthcare as it may inform the development of evidence-based telehealth programs, which can be tailored to specific chronic disease conditions and may provide policy makers with more efficient options for funding programs for chronic disease management.

Although promising, to establish the effectiveness of telehealth interventions and inform future programs, telehealth interventions need to be systematically evaluated against these traditional educational strategies and to standard care alone to prompt changes in healthcare policy that have been long suggested to deal with lacking compliance to lifestyle recommendations and other barriers in current chronic disease healthcare [10].

However, there is no existing or registered systematic review that has sought to assess the overall effectiveness of telehealth dietary interventions for facilitating complex dietary change in adults with chronic disease to date.

Objective

The objective of this review is to assess the effectiveness of telehealth as a strategy to deliver complex dietary interventions in adults with chronic disease.

Methods/design

Eligibility criteria

Study designs

Eligible designs will be randomised controlled trials (RCTs), cluster RCTs, and quasi-RCTs (RCTs using pseudo-randomisation). Trials which use crossover designs can introduce potential carry-over effects given the nature of dietary interventions to establish behaviour change; therefore, we will only include data from the first period of each intervention arm [34].

Participants

Adult participants (>18 years of age) with an established diet-related chronic disease which we define as obesity (BMI ≥30 kg/m^2), diabetes mellitus, established heart disease, hypertension, stroke, and kidney disease. These diet-related chronic diseases have been previously defined in a systematic review of dietary interventions [12]. We will review studies that report on a mixed sample, however, will only include participants with a chronic disease as defined above, and provided their results are reported separately to participants that do not meet our inclusion criteria.

Interventions

Eligible interventions will be those that provide a multifactorial dietary intervention using at least one telehealth strategy with a duration of at least 4 weeks. We define a multifactorial dietary intervention as targeting more than a singular nutrient and/or food group. Multifactorial dietary interventions include those aimed at overall dietary patterns, such as dietary guidelines [35, 36], the Mediterranean diet [37], and/or the DASH diet or those educating on two or more dietary components (nutrients and/or food groups) simultaneously. Studies that target two or more diet changes within the same nutrient (e.g. manipulation of categories of fatty acids) will be excluded as the dietary components only relate to one nutrient, and thus are not multifactorial.

Interventions that use either a single or multifactorial telehealth strategy will be eligible. Interventions that use both telehealth and non-telehealth strategies (e.g. face-to-face, group counselling) to provide dietary education will be eligible as long as at least 50 % of the total contact hours and/or the total number of interaction contacts with participants are delivered via telehealth methods. An example of an interaction is a text message, a phone call, log-on to a webpage, or a contact session with an intervention provider. Eligible interventions will be delivered by a qualified healthcare professional (such as a nurse, dietitian, or physician).

Comparators

The comparison group may have received usual care (as defined by trial authors); dietary education in a face-to-face or group-based environment with no telehealth component, or via a method in which less than 50 % of the intervention is delivered via telehealth; or a non-dietary focussed intervention.

Outcomes

We will only include studies that report at least two measures of dietary intake: at baseline and at least 4 weeks later at follow-up.

Primary outcomes:

- Dietary intake: any objective measure of dietary intake (such as diet quality score, servings of fruits and vegetables, and nutrient intake)

Although surrogate outcomes such as dietary intake cannot reliably predict clinical outcomes (e.g. mortality), dietary intake is the first line management strategy in chronic diseases [10]. It is clinically relevant to chronic disease as it may improve clinical outcomes and is a practical policy tool to inform the development of evidence-based telehealth programs, particularly for the chronic diseases listed above. Dietary intake is measured in a variety of units, and we have chosen not to restrict our primary outcome by unit of measure. Furthermore, this review may identify which outcome measures of dietary intake are stronger as surrogate markers of our secondary clinical outcomes.

Secondary outcomes:

- All-cause mortality;
- Cardiovascular mortality;
- Hospitalisations (total and those related to chronic disease);
- Any clinical marker of chronic disease progression, such as blood pressure, estimated glomerular filtration rate (eGFR), HbA1c, weight, waist circumference, and blood lipid profiles.

Setting

Studies will be eligible if the intervention is conducted in ambulatory or community settings (e.g. patients can be recruited during a hospital admission, but the telehealth intervention is delivered post-discharge). Studies that are solely conducted in hospitals or controlled conditions (e.g. where food and/or beverages are provided in full or partial) will not be eligible.

Language

No language restriction will be in our search strategy. We will attempt to translate potentially eligible non-English articles via Google Translate or by a native speaker of the language of the article. In the event that an article is eligible but unable to be satisfactorily translated, we will present the title and author details in a supplementary appendix.

Search methods

Electronic searches

A multi-step search approach will be undertaken to retrieve relevant studies. The following databases will be searched using a variety of subject headings, free text terms, and synonyms relevant to the review in consultation with an experienced search trials co-ordinator (see Additional file 1):

- MEDLINE (via OVID);
- CINAHL (via EBSCO);
- PsychINFO (via OVID); and
- EMBASE.
- Searches of the International Clinical Trials Register (ICTRP) Search Portal and ClinicalTrials.gov will be conducted to identify trials that are ongoing.

We will perform forward and backward citation searching of eligible studies. We will attempt to locate unpublished trials by contacting investigators known to be involved in previous studies that have not yet been published and by contacting published authors in the field of telehealth research and asking if they are aware of ongoing and unpublished trials.

Finally, we will perform a search for relevant theses and dissertations (via ProQuest) and conference abstracts (such as the annual meetings for the American Telemedicine Association, the International Conference on Health Informatics, and the Australasian Telehealth Society).

Selection of studies

All search results will be merged into reference management software EndNote, and duplicate records of the same report will be removed using the Centre for Research and Evidence Based Practice Systematic Review Assistant 'deduplication tool' [38]. Two review authors (JK and KC) will independently assess the eligibility of studies by screening titles and abstracts for potential inclusion according to predefined selection criteria. Studies judged to be potentially relevant will be retrieved in full text for further analysis. Any disagreements in judgement will be resolved by discussion to reach a consensus or if this is not possible, with a third review author (DR) until a consensus is reached. If further information about the study is required in order to make a decision about its eligibility, an attempt will be made to contact the study corresponding author(s). If a response is not received after three reminders are sent and/or after attempting to contact another author of the paper with no response, then the study will be excluded.

Data collection and analysis

Data extraction and management

Two independent authors will extract the data independently (JK and KC). Data will be extracted from all published reports of included studies using a data extraction form which will be piloted following adaptation from the Cochrane Effective Practice and Organisation of Care Group tool [39]. For all included studies, we will extract relevant data including all details about the intervention (following the components outlined in the Template for Intervention Description and Replication (TIDieR) checklist) [40], the participants (chronic disease state, age, and gender), attrition, and all our prespecified primary and secondary outcome data that are reported at baseline and follow-up. All extracted data will be transferred into Revman software (JK) and will be checked for accuracy (KC) prior to meta-analysis.

Assessing the risk of bias

Risk of bias will be assessed by two review authors (JK & KC) using the Cochrane risk of bias tool addressing the following elements that potentially affect risk of bias:

- Random sequence generation;
- Allocation concealment;

- Blinding—clients, providers, and outcome assessors;
- Incomplete outcome data;
- Selective reporting;
- Other bias.

Any disagreements in judgement will be resolved by discussion to reach a consensus or with a third review author until consensus is reached. We will tabulate and narratively describe the risk of bias in the included studies. For each study, we will categorise the risk of bias elements as low, unclear, or high risk. The effect that studies with a high risk of bias may have on the body of evidence will be explored in sensitivity analyses described below. We will consider the risk of bias for each outcome when grading the quality of the evidence.

Data analysis

The overall treatment effect for primary and secondary outcomes will be calculated from each trial included. The treatment effect will be calculated, where possible, as the difference between the intervention and comparison's change from baseline to the end of follow-up for each of the measured outcomes. Variance will be calculated for each treatment effect, either derived from the standard deviation or standard error from the difference between baseline and follow-up or from confidence intervals when these are not available [34].

Measures of treatment effect

Where the studies included have reported interventions and outcomes which are sufficiently homogeneous, and if there is sufficient information retrieved from the studies, quantitative data will be pooled into Revman (Version 5.3) for meta-analysis using the DerSimonian and Laird random-effects model [41]. Fixed-effect model will also be used to ensure robustness and susceptibility to outliers. Effect sizes (for continuous data; e.g. diet intake, biomarkers, blood pressure, and weight) will be calculated as mean differences (MD) or as the standardised mean difference (SMD) if different scales have been used, and their 95 % confidence intervals will be calculated to measure the treatment effect. The ratio of means (RoMs) is an alternate method for data pooling [42, 43] and will be alternatively used if the SMD cannot be calculated from the outcome measures extracted from the included studies. We will convert other forms of data into MD, SMD, or RoMs and calculate confidence intervals as required. Dichotomous outcome data (e.g. death, hospitalisations, and progression to renal replacement therapy) will be expressed as risk ratios (RR) with 95 % confidence intervals. We will convert other relevant binary data into an RR value. In the event of missing data, we will attempt to impute missing standard deviations or standard errors using data from other similar studies in the review utilising similar methods and sample sizes, as recommended [44].

Assessment of heterogeneity

We will assess the inconsistencies between studies using the I^2 statistic and describe the percentage of variability in effect. Heterogeneity will be considered substantial if the I^2 statistic is >50 %. We will use Egger's plot to assess and report on potential publication bias. We will consider a sensitivity analysis to explore statistical heterogeneity. The sensitivity analysis will be considered if the results of an individual study appear to be heterogeneous with the results of other included studies; repeat the analysis excluding unpublished studies; repeat the analysis excluding high risk of bias studies (method of randomisation, allocation concealment, blinding of outcome assessor, incomplete outcome data, selective reporting, other bias); and repeat the analysis excluding any long duration studies or large studies in order to establish how much they influence effect sizes.

Subgroup analyses

Depending on the included studies, we will conduct subgroup analysis to explore expected sources of clinical heterogeneity. Subgroup analyses will be considered on studies conducted in those with different chronic health conditions (e.g. diabetes, established heart disease, chronic kidney disease, and hypertension); studies using different telehealth strategies (e.g. Internet or mobile phone); studies with multiple telehealth modes of delivery (e.g. Internet and telephone) versus single mode; studies greater than 6 months versus less than 6 months duration; studies where dietary education is provided in the comparison group; studies targeting specified food groups or multiple nutrients (e.g. modifying sodium, fat, fruit and/or vegetables interventions) versus dietary patterns; and studies where dietary intervention is either the sole focus of an intervention versus as part of a complex multicomponent intervention (i.e. diet and exercise).

Presenting and reporting of results

This protocol follows the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 Statement [45] (see Additional file 2) . We will present the results of this review according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, using a flow diagram to report the identification and selection of studies, and assign a grading to the evidence using the GRADE tool. The relevant outcomes and characteristics of each study will be reported in summary tables. Where statistical pooling is not possible, the findings will be alternatively presented in a narrative form including tables and figures to aid in data presentation where appropriate. We will follow the Cochrane handbook guidelines for narrative synthesis, whereby grouping similar studies under headings (e.g. similar telehealth methods, dietary education, comparator studied (usual care and other dietary education delivery methods), chronic disease, dietary outcome measures) and report the direction, size and consistency of effect, and the overall quality of the body of evidence. For trials with more than one time point measurement for outcomes, we will only report results extracted from the furthest time points of the intervention.

Interpretation of findings

The results of the review will be discussed in the context of the quality of the evidence (GRADE), the limitations of the review, and the strengths of findings as well as their implications for current practice, future directions, and overall public health. To interpret the overall effectiveness of telehealth interventions and allow policy makers to effectively determine their efficacy at facilitating multifactorial dietary changes, we will also discuss the results in the context of the comparator studied (usual care and other dietary education delivery methods) as necessary given the retrieved body of evidence.

Discussion

This protocol for a systematic review of available evidence will establish whether telehealth is an effective strategy to deliver multifactorial dietary interventions in adults with chronic disease, which has not been previously evaluated or reviewed systematically. If telehealth is found to be effective in establishing multifactorial dietary change, this may inform a change in current clinical and public health practice by restructuring funding and resources for future chronic disease dietary management in healthcare. Furthermore, the primary results of this review and any long-term adverse consequences found by the review may be used to inform the development of evidence-based telehealth programs, best practice guidelines, and recommendations for future telehealth intervention delivery, which can be tailored to specific chronic disease conditions. This review will also identify any apparent gaps in the body of literature and highlight priorities for future research in the area.

Additional files

Additional file 1: Search strategy. Additional file 1 presents the MEDLINE search strategy which will be used to identify potential studies. (PDF 153 kb)

Additional file 2: PRISMA-P checklist. Additional file 2 presents the PRISMA-P checklist. (PDF 152 kb)

Abbreviations

BMI: body mass index; CVD: cardiovascular disease; DASH: dietary approaches to stop hypertension; eGFR: estimated glomerular filtration rate; GRADE: grading of recommendations assessment, development and evaluation; HbA1c: glycated haemoglobin; ICTRP: International Clinical Trials Register; MD: mean difference; MMS: multimedia message service; PRISMA: Preferred Reporting Items for Systematic Review and Meta-Analysis; PRISMA-P: Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols; Quasi-RCT: quasi-experimental controlled trial; RCT: randomised controlled trial; RoMs: ratio of means; RR: relative risk; SD: standard deviation; SMD: standardised mean difference; SMS: short message service; TIDieR: template for intervention description and replication.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

JK and KC were responsible for conducting the review and subsequent analysis. JK assisted in the conceptualisation of the review and drafted the study protocol. KC conceived the review and revised manuscript drafts. DR assisted in the conceptualisation of the review and reviewed all drafts of the manuscript. TH participated in the design of the review, provided methodological expertise, and reviewed drafts of the manuscript. All authors read and approved the final manuscript.

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Appendix B: Qualitative follow-up of experiences of the ENTICE-CKD program (draft manuscript; complimentary with Chapter 7)

ABSTRACT

Background: Dietary behaviour change interventions for self-management of chronic kidney disease (CKD) are required. Telehealth-delivered dietary interventions have shown to be effective for chronic disease management, although their acceptability is unknown in CKD populations.

Objective: This study investigates the acceptability and experiences of telehealth coaching using phone calls and tailored text messages to promote healthy eating and lifestyle in stage 3-4 CKD.

Design: Semi-structured interviews, transcribed verbatim and analysed thematically.

Participants/setting: Stage 3-4 CKD patients aged 28 to 78 years, who completed the first 12-week phase of the ENTICE-CKD trial (6 phone calls + 2-8 tailored text messages per fortnight + workbook) in Australia.

Results: Twenty-one interviews (mean 49 min) were conducted. Five themes were identified: valuing relationships (receiving tangible and perceptible support, building trust and rapport remotely, motivated by accountability, readily responding to a personalized approach, reassured by health professional expertise); appreciating convenience (integrating easily into lifestyle, freely talking in a familiar environment, minimizing travel and wait time burden); empowered with actionable knowledge (comprehending diet-disease mechanisms, practical problem solving for sustainable dietary behaviour); increasing diet-consciousness (learning from consistent feedback, becoming aware of dietary choices, prompted by reiteration of messages); making sense of complexity (overwhelmed by comorbidities, contextualizing and prioritising aspects of health, gaining confidence to make dietary decisions, setting and achieving realistic goals).

Conclusions: Individualized intensive telehealth coaching, using telephone and tailored text messages, is acceptable for promoting dietary self-management in stage 3-4 CKD. Participants valued the relationship built with their coach, the frequent contact and an individualized approach, and felt able to understand and implement practical dietary changes throughout the telehealth interventions. Future work is needed to determine why people do not participate in dietary and telehealth trials.

BACKGROUND

Chronic kidney disease (CKD) affects over 10% of the population worldwide,[1,2] and poses substantial burden for patients, families and the healthcare system. Among people with CKD, addressing dietary approaches is ranked as their top priority for research.[3,4]

Managing diet has previously shown to be associated with slowed progression of CKD.[5-7] There are many challenges in medical nutrition therapy for both dietitians and people with CKD, including restriction of specific nutrients, disease-related comorbidities, functional and social limitations, and cultural and personal preferences.[8,9] According to health professionals and CKD patients, frequent, individualized care is required for dietary behavior change[6,10] however, there are geographical, financial and time barriers to both providing and receiving care in CKD.[11,12]

Telehealth interventions overcome the geographical barrier between health professionals and patients and have shown to be effective in reducing chronic disease risk factors;[13,14] particularly through improving dietary intervention adherence and diet quality over face-to-face modalities.[15-17] Further benefits of telehealth include being able to facilitate an increased frequency of contact between the patient and healthcare professional,[13,16] which is desired by people with CKD as it allows regular feedback and incremental dietary changes.[10]

Given the lack of qualitative research in CKD,[18] and the complexity of CKD management, research into the acceptability of novel dietary and lifestyle interventions is warranted. Telehealth has been suggested as a possible dietary-delivery method to overcome common dietary challenges people with CKD experience.[19,20] To incorporate patient-centred care and inform future telehealth behavior change interventions in CKD, this study aimed to investigate the acceptability and the experiences of participants undertaking a telehealth-delivered dietary intervention in CKD.

METHODS

Context

This study is embedded within the **E**valuation of i**N**dividualized **T**elehealth **In**tensive **C**oaching to promote healthy **E**ating and lifestyle in people with stage 3-4 **CKD** (ENTICE-CKD) randomized controlled trial, overviewed in Figure B-1 and reported elsewhere (Chapter 7). Briefly, the 6-month trial involved an intervention workbook, face-to-face visits at baseline and endpoint, and telehealth coaching by a dietitian. The intervention group received fortnightly telephone calls and tailored text messages (2-8 per fortnight) for 12 weeks (phase 1), followed by tailored text messages only for 12 weeks (phase 2). Intervention text messages contained self-monitoring guidance, goal checks and educational tips. The control group were 'waitlisted' for 12 weeks and then received non-tailored educational text messages only for 12 weeks. The intervention aimed to reduce sodium intake and improve adherence to the Australian Dietary Guidelines[21] and Australian Physical Activity Guidelines[22] to prevent CKD progression. The telehealth intervention was built upon the framework of Social Cognitive Theory,[23] with a patient-centred focus on dietary self-management. This present study included intervention group participants who completion phase 1 of the ENTICE-CKD study. This study was approved by the Metro South Health Service District Human Research Ethics Committee (EC00167) and Bond University Human Research Ethics Committee (EC00357).

Participant selection

Stage 3-4 CKD patients (eGFR 15-60mL/min/1.73m^2) who owned a mobile phone were originally recruited for the ENTICE-CKD trial from three health districts in Queensland, Australia. All participants who completed the ENTICE-CKD intervention were eligible and invited for interview. Telehealth coaches consecutively sampled participants for semi-structured interviews as they completed the first 12-week phase of the trial. All participants provided written informed consent to complete an evaluation interview at baseline of the ENTICE-CKD telehealth intervention and additional verbal consent prior to interview.

Data collection

The interview guide (Appendix L) was developed based on literature and discussion among the research team.[3,24-27] The guide covered usability of telephone calls and text messaging, barriers and facilitators of actioning the telehealth intervention recommendations, and experiences of behavior change techniques involved in the telehealth intervention (e.g. goal setting). The first author (MW) conducted semi-structured interviews with each consenting participant by telephone or face-to-face from March to July 2017 at a meeting room separate to recruiting hospitals, as preferred by the participant. The interviews were recorded and transcribed verbatim. Interviews were continued until data saturation was reached.

Data analyses

Transcripts were entered and coded in qualitative data management software HyperRESEARCH.[28] Based on thematic analysis,[29] two researchers (MW and AT) familiarized themselves with the data line-by-line and inductively identified initial codes, which were discussed and refined to capture all concepts about the participants' acceptability and experiences of telehealth dietary and lifestyle coaching. The coding structure was used to develop themes within the data, which were refined and finalized through discussion. This form of investigator triangulation enhances the analytical framework and ensures that the full range and depth of data were captured in the analysis.

RESULTS

Participants

Of the 22 participants approached, 21 (95%) agreed to participate in this study. One person was unable to be interviewed due to travel commitments. The interviews ranged from 20 to 96 minutes (mean 49 min), and all except one was completed by telephone. Characteristics of participants are presented in Table B-1.

Themes

We identified five themes: valuing relationships, appreciating convenience, empowered with actionable knowledge, increasing diet-consciousness, and making sense of complexity. The subthemes are described below and selected quotations to support each theme are provided in Table B-2. Figure B-2 shows the thematic schema, highlighting the interaction and relationships between the themes.

Valuing relationships

Receiving tangible and perceptible support: Prior to the telehealth intervention, participants perceived a lack of support, stating that people are "too busy to worry" and not "really interested". They believed that the telephone calls and text messages during the program provided support and encouragement. They felt cared for by the coaches and were thus better prepared to accept their advice. For some participants, receiving the text messages meant - "you haven't been forgotten … it's like someone's out there thinking of you".

Building trust and rapport remotely: Participants developed a trusting relationship with their coach over the phone - "we're speaking … it's not like you're left hanging". Participants found the dietitian coaches "easy to talk to", "engaging", "positive", "approachable" and like "one of the family". They felt comfortable discussing their fears, such as medications and dialysis. The phone coaching sessions allowed time for questions, making participants feel heard and important without being rushed.

Motivated by accountability: Participants strived to adhere to dietary recommendations to improve wellbeing, self-satisfaction, or to impress their doctor, dietitian coach, family, or friends. Some were motivated to participate in the program because it was "for research," and thus expected they were contributing to improving the quality of healthcare for other patients with CKD. Having frequent contact and a good relationship with the dietitian coach made participants feel more accountable - "I knew I'd be getting another [text message] this week". Some participants felt they had a responsibility to write a food diary - "without the support or encouragement from someone else then self-monitoring can be just a word, or two words, but with the encouragement from that outsider, then those two words become important". Some participants discussed the program with family and friends, so they could be held accountable to reach their goals.

Readily responding to a personalized approach: all text messages were perceived as personable, particularly when the participant's or coach's name was included - "I was getting some [text messages] from [my coach] and I was getting some [text messages] that were computer generated … you could just tell that they were a bit more, perfect". Some participants felt each type of text message was necessary - "they're equally as important as the other, but for me I prefer getting a pat on the back than a suggestion of what I can eat".

Reassured by health professional expertise: Some participants felt that friends and family "don't understand" their situation, whereas their coach knew "about kidney health" and dietary management. Having ready access to a health professional (dietitian coach) was reassuring, and this fostered self-efficacy in some participants who then gained confidence to ask their doctor questions about their health condition(s). Participants trusted the information in the text messages and workbook and relied on these to guide their food choices between calls with their coach.

Appreciating convenience

Integrating easily into lifestyle: Participants noted that the flexibility in the schedule of the calls and the length of the calls did not disrupt their lifestyle. For example, they were still able to work, travel, and take care of family - "it was quite easy, that's what I enjoyed about it, was having that flexibility". Participants appreciated the ability to read the text messages in their own time - "you look at your phone any time … the message is always there".

Freely talking in a familiar environment: Participants were comfortable talking in their home, at work, or in the car as there were "no interruptions" and some were less "nervous" than facing a health professional in clinic. In contrast, participants had previously felt rushed in clinic and were conscious to avoid taking the clinician's time from "worse off people" seen in the waiting room. They also found it difficult to retain information that were relayed in the clinical setting - "you go there [into clinic], and you walk away, and you forget half of it".

Minimizing travel and wait time burden: Participants appreciated that they could access the program without travelling from remote areas, navigating public transport, finding and paying for parking, walking "a mile with an aching leg" from the car park, and dealing with the frustratingly long wait times at the clinic – "With the phone it's direct, it's immediate; in the clinic you go in, you go waiting … I've found the biggest problem is sitting around waiting to see somebody". The calls were "less hassle" than face-to-face and minimized the burden of clinic visits - "with all me other visits and you know, your normal life, it's pretty demanding to fit it all in".

Empowered with actionable knowledge

Comprehending diet-disease mechanisms: Participants were able to comprehend nutrition and disease mechanisms after more and more after each call, which raised self-efficacy and helped to justify food choices - "[my coach] took it a step further and not only explained what the big [nutrition] problems were but how they affect the kidneys". The workbook provided a "simple explanation of the technical stuff" and the new knowledge motivated participants to improve their self-management – "Now I'm aware of what was causing most of the problem, of course was most of the fluid intake, I'm trying very hard to still keep my fifteen hundred mls of fluid a day, and that seems to have worked".

Practical problem solving for sustainable dietary behavior: Participants found benefit in "just having a bit of information at a time, so it's not overwhelming". The coaches had "good ideas" and could suggest "little things" to change, such as "more veggie snacks between the meals". Some preferred to have a "clear cut" list of "good foods" and "foods to avoid" without the "long rigmaroles of why". After the coaching call on label-reading, participants believed they were more skilled at understanding food labels to make food choices – "I never ever looked at labels before, but, when you understand them, there's a big difference". Participants improved their nutrition intake by forming habits of: reading food labels; choosing lower sodium options; refraining from putting high sodium foods "in the trolley"; and having "the right foods in the house".

Increasing diet-consciousness

Learning from consistent feedback: Two weeks between calls was believed to be an optimal time frame for keeping diet and activity self-management at the forefront of the mind, as well as for reviewing behavior change and receiving feedback - "It's good to have someone to chat to every few weeks … you can go over any questions". Participants frequently brought dietary intake into their consciousness by keeping the workbook "in its spot" in a visible place and using it as a "reference" tool. The workbook was also "handy" for documenting thoughts and goals, and to "check on things" they had learned in the coaching sessions, such as high phosphate foods, food groups, and portion sizes.

Becoming aware of dietary choices: Some felt they had a high level of nutrition knowledge, however, using food diaries to raise awareness and bring diet "to mind" helped to put the knowledge into action. Becoming aware of their intake of fluid, high sodium foods, food groups and portion sizes was regarded as necessary for sustaining appropriate dietary habits - "I'm aware of like the salt intake and reading labels and that type of thing, which I've never been aware of before".

Prompted by reiteration of messages: Frequent text messages relating to the participants goals were "good reminders" and useful for "staying on track" to change habits. Reiteration of messages helped participants to take mindful action - "I sort of knew [the portion sizes], but they reinforce it all the time, which is a really good thing".

Making sense of complexity

Overwhelmed by comorbidities: Participants explained that comorbid conditions created physical and emotional challenges for changing diet and lifestyle behaviors, and for this reason, some did not adopt the physical activity component of the program - "I sort of have my problem where I can't walk because my hips get too sore and all that so yeah that wasn't sort of applicable to me".

Contextualizing and prioritising aspects of health: Participants reported that coaches "broke down" multiple "issues" into "simple basic understandings", and helped participants to prioritize health behaviors - "[my coach] pointed out the gout … he said to me you know we've got to look at all these things … get like the broader, you know the whole picture … I found that the coordination of the whole thing, looking at the total picture has been more helpful … I'm certain it's brought it all together for me".

Gaining confidence to make dietary decisions: Participants felt they were able to remember dichotomous and measurable dietary recommendations, such as: food swap list with ticks and crosses; food groups with number of serves per day; recommended portion sizes; and food label cut off points for particular nutrients. This quantifiable information empowered participants to make dietary decisions with confidence and to identify "which is good, or which is bad" about foods.

Setting and achieving realistic goals: Setting specific goals was well accepted for some participants who felt driven to "hit a target". As the participants could feel changes in their body and their goals progressed, they became more engaged with their coach and the telehealth intervention - "that's what encouraged me to go on [with the program], because I could see the change, as I was making little adjustments and they were only little adjustments, they weren't big adjustments … all these little adjustments amount to great leaps and bounds". Some participants wrote about their goals in the workbook and referred to them for motivation to continue their efforts. However, some did not like to write about their goals and behaviors because they considered it burdensome, did not enjoy writing, felt it was unnecessary because they were already aware of their behaviors, or they refused to be reminded of their kidney disease.

DISCUSSION

To our knowledge, this is the first study to provide patient insights into the acceptability and experiences of telehealth coaching for diet and in CKD. Participants reported positive experiences and overall acceptance of the fortnightly phone calls, tailored text messages and a workbook. Participants valued the relationship built with their coach over 12-weeks of contact as it increased their trust and confidence to discuss diet-disease mechanisms, goals, motivators, challenges and fears. The combination of frequent contact and an individualized approach empowered participants to speak freely with their coach, helping them to feel their diet-related comorbidities and lifestyle needs were thoroughly considered. Participants believed the coaches used their health professional expertise to prioritize and suggest practical dietary strategies.

Eliminating travel and wait times by allowing flexibility in telephone calls was appreciated because it enabled participants to incorporate the coaching into their daily life. Although participants desired the flexibility with telephone call scheduling, renal dietitians are time-poor[11] and the ability to remain flexible may be challenging for busy practitioners. Previous studies have shown that CKD patients feel rushed in clinic.[25] In contrast, participants who completed the ENTICE-CKD telehealth intervention felt there was ample opportunity to approach their coach.

Previously, interventions have been shown to be more effective when multiple intervention-delivery modalities are used.[16] Participants in this study felt it was necessary to receive a combination of telephone calls, text messages, and a hardcopy workbook because they used each differently for learning and motivating behaviour change. Similarly to the CKD patients in our focus group study,[10] participants were open to using text messages; however, some participants weren't in the habit of texting and didn't find the messages to provide additional benefit to the telephone calls and workbook. Others found great benefit from the text messages, due to increased interaction and support, greater accountability, and prompted behavior change towards goals -particularly when the messages were personalized with their personal goal, name or their coaches name. These findings strengthen the current evidence demonstrating the need for personalized text messages with tailored frequency in behaviour change interventions.[30]

The findings of this study highlight the importance people with CKD place on relationships, support and accountability. Although the ENTICE-CKD intervention did not formally include a dedicated intervention to address social support on social support, some participants found a range benefits in discussing their involvement and learnings from the program with family and friends, while others did not think to discuss it with others. Three specific behaviour change techniques within a 'social support' domain have been identified previously, including general social support, emotional social support and practical social support.[31] Future telehealth interventions which address dietary change may benefit from incorporating these social support components into the intervention content to further empower patients to change behaviors for disease management.

This study has important limitations to consider. *First, s*election bias is a likely limitation of this study as all participants had completed 12 weeks of telehealth coaching, thus CKD patients choosing not to participate in telehealth interventions may have differing opinions of telehealth coaching. Second, we did not interview participants in the control group (i.e. participants who did not experience the telehealth intervention). This means that participant's experiences with not receiving a telehealth intervention are not considered, and therefore it is difficult to interpret whether the positive experiences contrast with those participants that did not receive telehealth coaching. Third, the ENTICE-CKD intervention used mobile and telephone technologies and therefore this study is unable to determine whether people would have similar experiences with other telehealth methods. Future work should look to investigate how to engage people in dietary trials, and whether telehealth could assist in overcoming these barriers. Fourth, we could not utilise purposive sampling to recruit participants which may limit the generalizability of the findings in demographics which are different to the participants who participating in ENTICE-CKD.

Conclusions

In conclusion, individualized intensive telehealth coaching, using telephone and tailored text messages, is acceptable for promoting healthy eating and lifestyle in stage 3-4 CKD. Participants reported positive experiences and overall acceptance of the fortnightly phone calls, tailored text messages and hardcopy workbook. Participants valued the relationship built with their coach over 12-weeks of contact because it increased their trust and confidence to discuss diet-disease mechanisms, goals, motivators, challenges and fears. The combination of frequent contact and an individualized approach allowed participants to speak freely with their coach, helping them to feel their diet-related co-morbidities and lifestyle needs were thoroughly considered. Participants believed the coaches used their health professional expertise to prioritize and suggest practical dietary strategies, which were welcomed and actioned. Future work is needed to determine why people do not participate in dietary and telehealth trials.

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Conflict of interest, funding disclosure

The authors declare that they have no relevant financial interests.

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TABLES AND FIGURES

Table B-1. Characteristics of CKD patients participating in semi-structured interviews to investigate the acceptability and experiences of the ENTICE-CKD program.

Characteristic	Participants n (%)
Age	
<30	1 (5)
30-59	6 (29)
60-79	14 (67)
Gender	
Male	14 (67)
Female	7 (33)
Socioeconomic status[a]	
Low	8 (38)
High	13 (62)
Comorbidities	
Cardiovascular disease	16 (76)
Diabetes	6 (29)
Gastrointestinal conditions[b]	5 (24)
Bone and joint conditions[c]	8 (38)
Liver disease	1 (5)

[a] Socioeconomic status calculated from IRSAD score (Australian Bureau of Statistics, 2015), [b] reflux, diverticulosis, [c] gout, osteopenia, osteoarthritis.

Table B-2. Selected participant quotations for each theme

Theme	Selected Quotations
Valuing relationships	
Receiving tangible and perceptible support	You know someone's there, it's not like I'm going to phone you in two weeks' time, two weeks you're on your own, it's like someone's out there saying, you know, don't forget the salt, only put salt in, don't add salt on the table (Female, 60's) [My coach] supported me over the weeks, the phone calls every now and again, every couple of weeks or so, which I think's brilliant … just to have someone there to pat you on the back every now and again um and explain different things and things you don't think of and that sort of thing … I looked forward to the phone calls to tell you the truth! Because there's nothing better than talking to people (Male, 60's)
Building trust and rapport remotely	I was able to tell [my coach] my, you know, my personal life stories (Female, 60's) I suppose [talking on the phone is] the same thing [as going to clinic], if you get to know them, the more you talk to a person and get to know them a bit better, you sort of, you start to recognize their voice (Male, 40's)
Motivated by accountability	I made myself committed to that phone call, but everything else is how the person relates to you over the phone, how she talks or yeah, ah how you feel (Female, 60's) The ENTICE program is really motivating me, and when I go back to see [my nephrologist] on the 30th I want her to tell me that my kidney function has improved because of the program (Male, 60's) It was just getting someone there to keep reminding me to um, to stick to what I said I'd do (Male, 60's)
Readily responding to a personalized approach	The reality is every person is going to be different, and ah, I think the fact is that you talk one on one, like with [my coach] he can actually ah judge what your condition is and um change the program to um to actually what's happening to you rather than a generalization. I think it's important that ah, that it is personalized, 'cause you get that sense that well somebody's caring sort of thing, rather than just kind of generalization (Male, 70's) It is good that they make you feel like you're the only patient, kind of, that ah, you know, they're talking to you as a individual person, and I'm glad about that (Female, 60's)
Reassured by health professional expertise	[When it's] someone medical telling you, you seem to listen, so yes there are a lot of things that I have learned (Female, 60's) Having ah somebody that's got knowledge and experience and somebody saying this is what you can do, of course that's, that's very beneficial and it's having it regular (Male, 40's) [My coach] knew what she was talking about basically, and she's easy to talk to, so, and explain things well to you (Male, 60s)
Appreciating convenience	
Integrating easily into lifestyle	It was convenient for me, I could just do it from home, I didn't have to go and go anywhere I could just receive calls and, and reminders you know as they come along (Male, 60's) It's good you don't have to go to the dietitian either, see he rings you, wherever I am and whatever I'm doing, we've made time for it, cause otherwise you've got to get in the car and go to the dietitians office and the hospital, well see my hospitals over half an hour from here sort of thing so it's a bit of a pain to go up there, it'd be a pain to go up every week too (Male, 50's) It's been pretty easy because I haven't had to go out of my way to do anything really, because like I said I can be quite busy with work and things like that so I haven't had to sort of worry about doing anything extra on top of everything else, (Female, 30's)

Theme	Selected Quotations
Freeling talking in a familiar environment	With the phone, it's immediate, completely straight away, you're talking to somebody, you've got a suggestion, you've got you know what you need to do all mapped out, say thank you very much and hang up and move on, in all of five minutes you know and you haven't left the comfort of your own home (Male, 60's) Actually sometimes it's easier when it's not face to face … like when I go and have my HbA1C [diabetes check] done every 3 months and then I've got to go and see [my doctor], and I don't know the results, I'm a bit, I'm a bit nervous face to face with him … but if I just had to talk to him on the phone it would be easy (Female, 60's) [At home] that was the best way to do it … you've got the book in front of you if she wants to refer to something it um, it's quieter and peaceful so the speak (Male, 60's)
Minimizing travel and wait time burden	Well I live a long way from the clinic yes, I'm roughly an hour and a half away. If I had to go in every day, every week, I probably wouldn't have been able to do it. The cost of fuel would have been too much (Female, 60's) You've got to walk a kilometer up to the hospital and meet a deadline. So, you know I might leave an hour earlier and just still make it, but you can ha, sometimes leave an hour earlier and get a park and sit there for an hour, and so all those sorts of things affect your attitude, ah and you're not really concentrating and you don't think of ah, you know you're probably of how your ankles hurting and how your, you know where's the toilet when you get out of here (Male, 70's) It's the modern world, people just ah just can't take time out to go and have a one-on-one hour consultation here and there, and um having [my coach] you know just ah, his approach over the phone is just like hey, and ah this is, I'm pretty comfortable with this (Male, 40's)
Empowered with actionable knowledge	
Comprehending diet-disease mechanisms	It's not something you can sit down with a dietitian for a, an hour once every three months because you just, don't get that, you just can't… get all the information from that short period of time (Male, 40's) [my goal] was to stop drinking a lot of milk, 'cause [my coach] sort of explained it to me, like what milk does and like how it is and stuff and even like the sodium content, which like when she was teaching me to read labels, I went over, had a look and realized you know having a little bit is ok but 3 litres a day is really bad (Male, 20's)
Practical problem solving for sustainable dietary behavior	I do read the tags on stuff that I'm going to eat and I'm very aware of the salt content in just about everything I eat now. But I wasn't before. Ok to me it was just sodium, and sodium doesn't mean anything to me. But when it's broken down and says well sodium is salt and this is what it does, um well this is when I understand that you can't have too much (Male, 60's) Working late and things like that I'd just sort of make sure that I've got different food there to tie me over and how I'd go about that and [my coach] thought of different things that were really good ideas (Female, 30s) I'm a simple person and ah I can only understand simple tasks, and one task at a time, give me too many tasks and I freeze over (Male, 60's)
Increasing diet-consciousness	
Learning from consistent feedback	I think once a fortnight's pretty good because it gives you time to adjust to if she has um wanting to test ideas anyway, so you'd sort of tell her how we're going if you adjusted to them so it gives you a couple of weeks to ah, try them out so to speak (Male, 60's) Having [the fortnightly phone calls] was very beneficial, I felt like um, ok, 15 to 20, 25 minutes depending on the topic, ah, was very beneficial, um, it's good to have … that backup, having that person to talk to, to go back to, um query what are you doing, is it right and um, and how to improve. It's good to have that … its having it regular, not just that 'ah well I've got to go and see the dietitian now and then I won't see them again for another 6 months … It's like an onion peeling back, just peeling back layers and layers and layers, [the workbook is] always there, it's a great resource … I've been refreshing myself and going back and looking at it (Male, 40's) Have someone there to pat you on the back every now and again um and explain different things and things you don't think of (Male, 60's)

Theme	Selected Quotations
Becoming aware of dietary choices	If I sort of got to a time in the evening and I wanted something you know like rubbish like chocolate or something, I'd try and think of, think through what I'd eaten through the day and had I met all my um, dairy or fruit servings and everything for the day and if I hadn't I'd have one of those instead (Female, 30's) I'm very glad that the awareness is a thing that I get out of this is that people aren't aware of the potassium's and the phosphates and the reason the salts and sugars should be very carefully looked at (Male, 70's) Just being aware that the sizes, the size needed to be smaller, um, we do have several sized bowls at home so you know going to a smaller bowl was a help (Female, 60's)
Prompted by reiteration of messages	He sends me all these messages ... once you get out of the habit with all these reminders it, it's a good thing (Male, 60's) In [the] texts for the fortnight post suggestion, [my coach] would say 'how are you going with your no potato chips' and that sort of thing and then he would give me a little reason why it's a good thing not to have so much salt (Male, 60's) [The text messages are] just that little back up think to keep you on track you know it, I think because I wasn't seeing him all the time or talking to him every week, yeah I think it's a good idea, it just keeps your mind, especially in the beginning, it keeps your mind on track about what you're trying to do (Female, 60's)
Making sense of complexity	
Overwhelmed by comorbidities	I've had a few sicknesses in the last 3, oh about the last 4 months actually I've had 2 eye infections … I've had a lot of stress in the 2 months or so, so my sugar levels have not been really good, I panicked a bit but again, [my coach] just sort of said look don't give yourself more anxiety by worrying about it (Female, 60's)
Contextualizing and prioritizing aspects of health	Very helpful, because it was all broken down into simple terms! I don't need great big technical words that mean exactly the same thing, if you give me something simple to do, I can get it done, and that's what the program has done … We're all layman out here… the ENTICE program, and [my coach], always put his words in simple, simple terms (Male, 60's) It's made me understand my kidney malfunction a lot more than I did before I started. To me my kidneys were retaining fluid and it was leaking out into my muscles, and that was it, that was the end of it, but now I understand why it's happening (Male, 60's)
Gaining confidence to make dietary decisions	I'm quite pleased I actually, it gave me a better understanding of what to do um, and you sort of feel that you are a bit ah you know how to eat and you know what to do but you don't! If you understand what I mean? Like you should have this, there's vegetables, you've got to eat these foods, food groups and that, but you, and you don't actually know the right quantities and things like that, that's where this program shows it to you, and it's like, it's teaching someone how to walk again, how to walk properly (Male, 40's) Yeah I learned how to read those labels a bit better, I knew the labels were there but I didn't really understand them and I kind of know how to read the labels now, which is handy, so it has benefited me (Male, 50's)
Setting and achieving realistic goals	I set [the goals] at the beginning and then um, and then in the next catch up call we'd see how I was going with them and usually, the whole way through I sort of maintained the same goals that I set at the beginning but I'd add to them each fortnight ... one of the first goals that I set was to have um, fruit and yogurt because my dairy was down a serve and my fruit was down quite a bit, so I'd have fruit and yogurt together and then later on I found out that I needed some more um, grains ... and then there was another one to up my fibre, so I set it to have more ah raw vegetables (Female, 30's) Giving up that soft drink was pretty hard! … when we first started off I was having a bit too much but I've cut down, but I cut down and I've really cut down now … the first month I was still sneaking them in, but I've slowly cut back and found the taste for water (Male, 50's) I was eating an incredible amount of white bread, half a dozen large slices a day … and through his texts and information and the ENTICE book, he suggested I go onto grained bread, I did that and I still had my six slices of bread a day and, over a period of time he said well let's see if we can make a goal, he said would you like to try and cut back on your bread? Ah and I've in fact done that, I'm down to 2 or 3 slices of bread a day now (Male, 60's)

Screening and recruitment

↓

	Week	**Intervention group** (n=40)
Phase 1	1	Baseline Visit
	2	
	4	6x fortnightly telephone calls + tailored text messages (2-8/fortnight) + workbook
	6	
	8	
	10	
	12	End of coaching; invited for semi-structured interview

Figure B-1. Summary of ENTICE-CKD program delivery. Semi-structured interviews were completed with intervention group participants who had completed phase 1 of the ENTICE-CKD trial.

Appendix C: Patient-engagement survey (complementary with Chapter 6)

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RESEARCH ARTICLE Open Access

Evaluating the prevalence and opportunity for technology use in chronic kidney disease patients: a cross-sectional study

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Abstract

Background: Chronic kidney disease (CKD) is increasing worldwide and early education to improve adherence to self-management is a key strategy to slow CKD progression. The use of the internet and mobile phone technologies (mHealth) to support patients is considered an effective tool in many other chronic disease populations. While a number of mHealth platforms for CKD exist, few studies have investigated if and how this population use technology to engage in self-management.

Methods: Using a cross-sectional design across five health districts in Queensland (Australia), a 38-item self-report survey was distributed to adults with CKD attending outpatient clinics or dialysis units to measure current use and type of engagement with mHealth, perceived barriers to use, and opportunities to support CKD self-management. Odds ratio (OR) were calculated to identify associations between demographic characteristic and mHealth use.

Results: Of the 708 participants surveyed, the majority had computer access (89.2%) and owned a mobile phone (83.5%). The most likely users of the internet were those aged ≤ 60 years (OR: 7.35, 95% confidence interval [CI]: 4.25–12.75, $p < 0.001$), employed (OR: 7.67, 95% CI: 2.58–22.78, $p < 0.001$), from non-indigenous background (OR: 6.98, 95% CI: 3.50–13.93, $p < 0.001$), or having completed higher levels of education (OR: 3.69, CI: 2.38–5.73, $p < 0.001$). Those using a mobile phone for complex communication were also younger (OR: 6.01, 95% CI: 3.55–10.19, $p < 0.001$), more educated (OR: 1.99, 95% CI: 1.29–3.18, $p < 0.01$), or from non-indigenous background (OR: 3.22, 95% CI: 1.58–6.55, $p < 0.001$). Overall, less than 25% were aware of websites to obtain information about renal healthcare. The mHealth technologies most preferred for communication with their renal healthcare teams were by telephone (56.5%), internet (50%), email (48.3%) and text messages (46%).

Conclusion: In the CKD cohort, younger patients are more likely than older patients to use mHealth intensively and interactively although all patients' technology literacy ought to be thoroughly assessed by renal teams before implementing in practice. Further research testing mHealth interventions to improve self-management in a range of patient cohorts is warranted.

Keywords: Mobile phone, Internet, Smart phone, Telehealth, E-health, mHealth, Chronic kidney disease, End stage kidney disease

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Background

Self-management requires individuals to know how to monitor their disease, manage symptoms, interpret results of home-monitoring therapies, and to carry out daily treatment plans including adhering to complex medication regimens, dietary and fluid restrictions, and for some, perform dialysis at home. To enable people with CKD do this, renal clinicians (and others) use a range of educational and behavioural strategies to support self-management behaviours. However, clinicians largely believe that if people have adequate knowledge about what to do, they will engage in self-management behaviours [1]. This is problematic because adequate understanding of CKD and its management remains bewildering for many who are attending specialist renal services [2–5].

Technologies such as smart phones, tablets, laptops, and other transportable devices are being increasingly used to deliver information and educational support programs to patients. eHealth includes a wide range of devices and technologies (including websites, robotics, alarms, and communication platforms) for the monitoring, detection, management and treatment of individuals [6]. A component of eHealth, 'mHealth' has more recently been coined as a term describing the use of mobile and wireless devices, exploiting the ability to speak and message in real time [7]. Phone 'Apps' as a type of mHealth have also become valuable tools as medication alarms and reminders, monitoring devices, and scheduling and education delivery systems [8]. The millennial term, 'digital divide', refers to the socioeconomic or age-related inequality of internet access and technical literacy [9]. This is a serious issue impinging on the use of mHealth, as many technologies assume levels of computer knowledge and unrestricted internet access that may not exist.

Internationally there are a number of educational websites to inform people about CKD and its risk factors, treatment options along the course of the disease trajectory, as well as related diseases [6, 10]. However, those with CKD are less likely than healthy adults to access the internet [11, 12] or even know that information is available [2, 6]. Determinants to internet access in the CKD population include: access to a computer, technological literacy, and income and education levels [10, 11]. In those receiving haemodialysis (HD), previous studies show that access the internet is 35% and 58% in the United States and Canada respectively [13, 14]. Moreover, clinicians tend to over-estimate patient access to and use of these technologies to manage their health [15, 16].

The use of and potential for mHealth has not been established in the Australian CKD population. Prior to developing mHealth applications for this group of patients, this study sought to understand whether and how individuals were accessing and using mobile phones and the internet; and whether they used the internet to gather any renal information. Knowledge of these determinants will help identify the most effective education platforms for this patient population.

Methods

Using a cross-sectional design, this study was conducted at five renal services (2 regional, 3 metropolitan) in Queensland, Australia. Inclusion criteria were: > 18 years; attending a CKD outpatient clinic (regardless of CKD stage) or dialysis unit with end-stage kidney disease (ESKD); and able to read and write English, or have a family member who could assist with the completion of the survey. People with a cognitive impairment, limited English language ability or who had a functioning kidney transplant were excluded from the study. Data was collected over a nine-month period between June, 2015 and March, 2016.

Sample size

Utilising the most conservative 'rule of thumb', 20 participants per item determined the study sample size [17, 18]. This study therefore required a minimum of 380 participants.

Instrument

Data was collected using a 38-item survey which assessed factors associated with internet and mobile phone use; barriers to access; types of information accessed; and why and how information is accessed (see Additional file 1). It was developed by the researchers after a thorough investigation of the literature revealed important topics and issues relating to patients' information needs and technology use. Items were a mixture of multiple choice and short answer; such as "How often do you access the internet?"; "Have you ever used the internet to find information about your kidney health condition?"; "Do you use your mobile phone for any of the following activities?" The survey was designed to be easily understood and completed by those with low literacy levels (accessible to those at a primary school reading level ability or above). It was first tested on a sample of ten patients (who were not part of the main study) who reported no difficulty in responding to items; it was then implemented without alteration. Self-reported demographic characteristics (age, gender, level of education, employment status, and postcode) were also collected. Due to the high prevalence of CKD in the Australian indigenous population [19], participants were also invited to indicate whether they identify themselves as 'Aboriginal', 'Torres Strait Islander', or both, and have therefore been grouped under the classification ATSI (Aboriginal and/or Torres Strait Islander). Surveys were completed in the waiting room of the renal outpatient clinic or dialysis unit and returned by placing in a secure box or completed at home and returned in reply-paid envelopes.

Data analysis

Statistical analysis was performed using IBM SPSS Version 23.0 [20]. For analysis we grouped age into 18–40, 41–50, 51–60, 61–70 and > 71 years. Education level was divided at those who did and did not complete high school, as year 12 completion is an indicator of continuing further education [21]. Categorical variables were described using frequencies and percentages, and bivariate relationships were explored using chi-square analysis. We defined mobile phone use as: i) simple (only making voice calls and short message service [SMS] sending and retrieval); ii) complex (simple use plus sending photos/videos, playing music/games, using phone calendar); and iii) complex apps (use of phone applications such as banking, social media, email, skype, online bookings, shopping).

Binary logistic regression was used to determine strength and direction of relationships and to allow for adjustments of demographic variables (age; gender; education; ethnicity; employment; and remoteness [determined by postcode]). Odds ratios (OR) and 95% confidence intervals (CI) were reported. Multivariable models, to identify factors influencing the use of mobile technologies and health information access, were created using forward stepwise modelling using demographic variables. This modelling technique was chosen based on the number of variables, and the high likelihood of multicollinearity in this subset of variables. A significance level of $p < 0.05$ was used.

Results

Initially 720 surveys were collected across all sites although 12 (1.7%) were excluded due to incompleteness (< 80% of questions were answered, and/or crucial questions relating to internet and mobile phone use, fundamental to the research question, remained unanswered). In total, 708 completed surveys were used in the final analysis. Just over half of the sample was male (55.2%) and about half were aged > 61 years (51.6%). The largest portion was 71 years of age and over (29.3%). The majority of participants (83.1%) were not Aboriginal or Torres Strait Islander (non-ATSI), while 11.7% self-identified as ATSI. See Table 1 for demographic characteristics.

Mobile phone use

Most of the sample owned a mobile phone ($n = 588$, 83.5%); with most reporting that it was a smart phone ($n = 378$, 64.3%) although 4.9% ($n = 29$) were unsure. More than half ($n = 456$, 77.6%) could use the phone for complex activities although this was mostly due to taking photos. Fewer indicated that they could use mobile phone apps ($n = 215$, 36.6%). Mobile phone ownership

Table 1 Participant demographics

	Number	Percent
Site		
Site 1 (Metropolitan)	243	34.3
Site 2 (Metropolitan)	137	19.4
Site 3 (Metropolitan)	143	20.2
Site 4 (Regional)	104	14.7
Site 5 (Regional)	81	11.4
Gender		
Male	389	54.9
Female	316	44.6
Missing	3	0.4
Age		
18–40	119	16.8
41–50	108	15.3
51–60	115	16.2
61–70	158	22.3
71+	207	29.2
Missing	1	0.1
Ethnicity		
ATSI	78	11.0
Non-ATSI	588	83.1
Prefer not to indicate or missing	42	5.9
Employment		
Employed (F/T and P/T)	161	22.8
Unemployed	36	5.1
Pensioner / Retired	439	62.2
Other (Student/home duties)	70	9.9
Prefer not to indicate or missing	2	0.3
Education level		
Did not complete high school	346	48.9
Year 12 or equivalent	345	48.7
Prefer not to indicate or missing	17	2.4
Region / remoteness		
Major City	451	65.3
Inner Regional	129	18.7
Outer Regional and remote	111	16.1
Prefer not to indicate or missing	17	2.4
Currently receiving dialysis		
Yes	269	38.5
No	429	61.5
Type of dialysis		
Haemodialysis in hospital or satellite unit	219	81.4
Haemodialysis in the home	26	9.7
Peritoneal dialysis in the home	18	6.7
Missing	6	2.2

ATSI aboriginal and Torres Strait Islander, *F/T* full-time, *P/T* part-time was significantly more common in those ≤60 years of age ($p < 0.01$), employed ($p < 0.01$), and those with higher education levels ($p < 0.01$). There were no differences for either ethnicity or whether or not on dialysis (see Table 2).

Multivariate binary logistic regression showed significant relationships between complex use and age, ethnicity, and education levels (see Fig. 1a). Participants aged ≤60 had over six times the odds of using their mobile phone for more complex tasks than did those aged 61 and over (OR: 6.01, CI: 3.55, 10.19, $p < 0.001$). Non-ATSI participants had over three times the odds of complex phone use than did those who identified as ATSI (OR: 3.22, CI: 1.58, 6.55, $p = 0.001$). Those who had obtained higher levels of education had almost double the odds of complex use (OR: 1.99, CI: 1.24, 3.19, $p = 0.004$).

Approximately one third (29.5%) of participants reported that they had downloaded at least one mobile phone application (e.g. Twitter, banking) in the past month. When examining the complex apps use as a demonstration of greater mHealth literacy, a similar relationship was demonstrated between app use, age, education, and employment; though employment was seen to be more of a predictor than ethnicity (see Fig. 1b). Younger participants (≤ 60 years) had over four times the odds of complex app use (OR: 4.25, CI: 2.67, 6.76, $p < 0.001$), while those who were employed (OR: 1.83, CI: 1.15, 2.89, $p = 0.01$) and those who had obtained higher levels of education (OR: 2.35, CI: 1.54, 3.58, $p < 0.001$) had approximately twice the odds of complex app use.

Table 2 Mobile phone ownership within demographic groups; chi-square analyses

Demographic Characteristics	Own A Mobile Phone Frequency (%)	Do Not Own Mobile Phone Frequency (%)	p
Age[a] ($n = 703$)			
60 and under	320 (94.1)	20 (5.9)	< 0.01
61 and over	267 (73.6)	96 (26.4)	
Ethnicity[a] ($n = 664$)			
ATSI	60 (76.9)	18 (23.1)	0.11
Non-ATSI	493 (84.1)	93 (15.9)	
Employment[a] ($n = 702$)			
Employed	156 (97.5)	4 (2.5)	< 0.01
Retired/ unemployed	430 (79.3)	112 (20.7)	
Education[a] ($n = 687$)			
Did not complete high school	271 (78.6)	74 (21.4)	< 0.01
Grade 12 and over	305 (89.2)	37 (10.8)	
Dialysis[a] ($n = 694$)			
On dialysis	226 (84.3)	42 (15.7)	0.67
Non-dialysis	354 (83.1)	72 (16.9)	

ATSI Aboriginal and Torres Strait Islander [a] analysis conducted on available data

Internet use

Of the total cohort who reported using the internet ($n = 491$, 69.4%), most used it at home ($n = 379$, 89.4%) for more than 60 min per day ($n = 252$, 51.9%) through a laptop ($n = 113$, 32.3%) or desktop computer ($n = 107$, 30.6%). The most frequently reported internet activities were checking emails ($n = 395$, 80.9%), searching/browsing the internet ($n = 366$, 74.5%), accessing social networks ($n = 245$, 50.2%), accessing health information ($n = 221$, 45.3%), and reading/watching the news ($n = 217$, 44.5%). A total of 217 participants (30.6%) reported that they did not use the internet, of those more than half ($n = 118$, 54.4%) reported that they did not know how to use the internet. A large number of participants also indicated that hospitals should provide free access to WiFi ($n = 464$, 70.3%).

Binary logistic regression modelling (see Fig. 1c) indicated that four factors impacted on people's odds of having used the internet: age (participants ≤ age 60 had over seven times the odds of having used the internet, OR: 7.36, CI: 4.25, 12.75, $p < 0.001$); employment (OR: 7.67, CI: 2.58, 22.78, $p < 0.001$); education (OR: 3.69, CI: 2.38, 5.73, $p < 0.001$); and ethnicity (OR: 6.98, CI: 3.50, 13.93, $p < 0.001$).

Searching the internet for information related to CKD

Just under half of the sample ($n = 332$, 49%) reported that they had used the internet to seek specific information regarding their CKD. Only 189 participants (27.4%) reported that their family had sought information about CKD on the internet on request. Those seeking health information online were younger ($p < 0.01$), less likely to be indigenous ($p = 0.03$), and more likely to be employed ($p < 0.01$) and have obtained higher educational qualifications ($p < 0.01$). There was no difference between those who were or were not receiving dialysis (see Table 3).

As age increased, there was a significant reduction in the use of the internet to seek health information regarding kidney 'problems' (renal impairment); from 78.8% ≤ age 40), decreasing steadily to 19.1% (≤ age 70; $\chi2(4) = 137.389$, $p < 0.01$). Older participants were less likely to have known of any websites for kidney patients, though no age group had an explicit knowledge of these sites (37.9% of those ≤40, decreasing to 10.8% of those > 71 ($\chi2(4) = 44.723$, $p < 0.01$). Participants were also more likely to have heard of kidney websites if they were on dialysis (31.9% versus 19.7%; $\chi2(1) = 12.867$, $p < 0.01$).

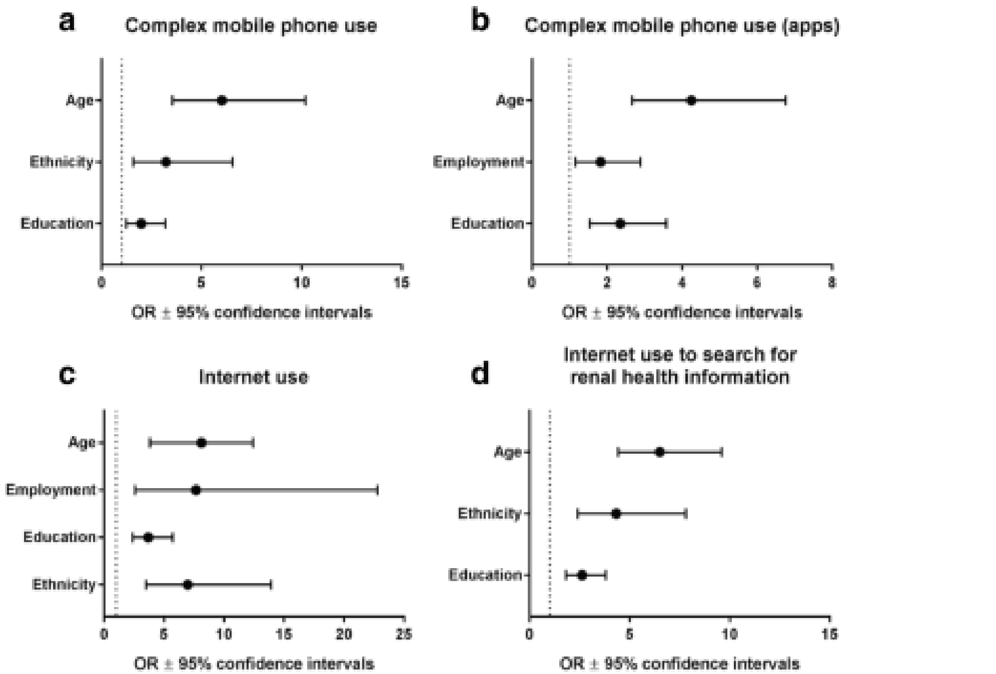

Fig. 1 Logistic regression model for odds of mobile phone and internet use. Odds ratios ±95% confidence intervals derived from logistic regression for **a)** complex mobile phone use; **b)** complex mobile phone use (apps); **c)** internet use; and **d)** internet use to search for renal health information. Dashed line at x = 1 indicates referent group (age > 61 years; ethnicity = ATSI; education = less than 12 years of schooling; employment = retired/unemployed)

Table 3 Participants who use the internet to search for renal health information; chi-square analyses

Demographic characteristics	Used the internet to seek renal health information Frequency (%)	Did not use the internet to seek renal health information Frequency (%)	p
Age[a] ($n = 675$)			
60 and under	235 (70.1)	100 (29.9)	< 0.01
61 and over	97 (28.5)	243 (71.5)	
Ethnicity[a] ($n = 640$)			
ATSI	25 (33.8)	49 (66.2)	0.03
Non-ATSI	296 (52.3)	270 (47.7)	
Employment[a] ($n = 674$)			
Employed	114 (72.2)	44 (27.8)	< 0.01
Retired/ unemployed	218 (42.2)	298 (57.8)	
Education[a] ($n = 662$)			
Did not complete high school	110 (33.6)	217 (66.4)	< 0.01
Grade 12 and over	219 (65.4)	116 (34.6)	
Dialysis[a] ($n = 667$)			
On dialysis	127 (50.4)	125 (49.6)	0.71
Not on dialysis	203 (48.9)	212 (51.1)	

ATSI Aboriginal and Torres Strait Islander [a] analysis conducted on available data

Figure 1d illustrates the impact of age, ethnicity and education on searching the internet for renal health information. Younger participants had 6.5 times the odds of having used the internet to seek for renal health information (OR: 6.51, CI: 4.42, 9.59, $p < 0.001$). Non-ATSI and more educated participants had over 4 times the odds (OR: 4.33, CI: 2.41, 7.79, $p < 0.001$) and 2.6 times the odds (OR: 2.62, CI: 1.81, 3.78, $p < 0.001$), respectively.

Facilitators and barriers to mHealth

When participants were asked what mHealth technologies they would be willing to use to engage with their healthcare team, the most common modalities indicated were telephone calls ($n = 400$, 56.5%), followed by the internet ($n = 354$, 50%), email ($n = 342$, 48.3%) and SMS messages ($n = 326$, 46%; note: participants could indicate more than 1 modality). Overall the perceived barriers to using technologies were low although the barrier 'do not know how to use' was indicated more frequently for SMS messages ($n = 94$, 13.3%), emails ($n = 112$, 15.8%) and visiting a website ($n = 108$, 15.2%).

Discussion

To our knowledge, this is the first study to identify the use of mHealth in an Australian population of CKD patients. We found that patients older than 60 years, those from an ATSI background, and those with lower levels of education (did not complete secondary school) were engaging in only simple communications functions with their mobile phones. Whereas younger, more educated and employed patients could undertake more sophisticated activities with their mobile phones and were also more likely to use the internet. Our findings also indicated that, regardless of age, the level of access to technology (including mobile phone ownership) was high. While new technologies for mHealth are being developed rapidly to improve education, treatment, and service delivery for patients with a range of chronic diseases [6], our findings indicate that a large number of patients with CKD will be alienated from and excluded if there is a uniform move to adopting these technologies.

In other chronic diseases such as heart failure, diabetes and chronic obstructive pulmonary disease (COPD), mobile phones are frequently used to deliver patient education and self-management support [22–24]. When utilised, mHealth (reminder services, systems, or booking systems) can have beneficial impacts on health care costs, self-efficacy, and clinical outcomes such as blood pressure and glycated haemoglobin A1c [24–26]. Although a number of studies have described the benefits of these interventions, several systematic reviews have found that the results of these studies were small or inconclusive [22, 24, 27–29]. High attrition rate is the major issue facing many studies investigating technologies, with up to 78% of participants failing to use, or rarely using the technologies being investigated [27, 30]. The common pattern of attrition in these studies has often been explained by technological difficulties faced by participants, the increased time burden of technology interventions, and costs involved in maintaining these services [31, 32]. Nevertheless patient-reported barriers to mHealth tend to be due to technical problems or having an aversion to using technology, and that is still a preference for face-to-face interaction with health care providers [27]. Simple, less time-consuming technology which is user-friendly is more likely to be acceptable in those with chronic disease [33].

Previous studies in kidney transplant recipients [9], and other chronic diseases [15, 34] have also found that sociodemographic characteristics (age, education level, ethnicity) influences internet use. Our study found a low prevalence of barriers related to a lack of knowledge on computer use, disinclination or unwillingness to use, and no access to a computer, reflecting the potential for a digital divide in this population. These reasons are comparable to the 2014–15 Australian Bureau of Statistic (ABS) figures; reporting the main reasons for no computer access as no need (63%), lack of confidence or knowledge (22%), and cost (16%) [35]. Access to technology is associated with higher socioeconomic levels (e.g. level of education and income. Park [36] argues that there is a 'double jeopardy' of social exclusion and geographical remoteness contributing to the digital divide in Australia. Regardless of location, the digital divide is further exacerbated because the acquisition of digital literacy skills are either not acquired or developed alongside the growth of technology in everyday life. For those not using these technologies, traditional methods of education and service delivery ought to be retained.

Another possibility for low adoption of online services and sites is that they are not tailored to suit the general public's digital and health literacies. Being able to locate and navigate online sites can be challenging, and then layering on the need to comprehend CKD-specific information adds further complexity. CKD websites and YouTube vary greatly in the amount and type of information provided, and these are rarely written at a literacy level easily understood by the average CKD patient [37–39]. In a review of eHealth studies, Irizarry [40] found that higher health literacy capability contributed to the greater use of technology, indicating that those not participating in online services or programs would benefit the most from additional face-to-face information and support. Our results contribute to the importance of including CKD patients when developing mHealth strategies. This approach is likely to improve useability and uptake by a wider group of patients because the language, navigation, interface, and content, reflect a broader range of digital and health literacy capabilities [40].

There are currently a wide variety of online and mHealth interventions, 'apps', monitoring and communication services, educational websites, forums, patient portals and many more. There is no one superior model for mHealth delivery and clinicians ought to select the one most appropriate to their patient population. Ease of use for the patient (and clinician) is likely the most critical feature that dictates uptake and use of these technologies [32]. The findings for our study indicate that while many participants would be willing to use online sources and services for their care, capability must be thoroughly assessed prior to implementing as a strategy for supporting self-management.

Limitations

The strength of this study was that the large sample included both non-dialysis and receiving dialysis, those attending renal services in both metropolitan and regional areas, and ATSI people with CKD. The non-dialysis group in this study were similar in age, gender and ethnicity to those in the CKD Queensland registry [41]. For those who were receiving dialysis age, ethnicity, and mode of haemodialysis were consistent with the Australian ESKD population in the Australian and New Zealand Dialysis and Transplant registry although this study had fewer peritoneal dialysis patients [42].

However, there are limitations of this study. First, kidney transplant recipients were excluded from this study warranting further research for this group of patients. Second, the instrument could have been designed with either additional age groups (e.g. 81+, etc) or capture a date of birth. Lastly, data was all self-reported and subjected to recall bias. As CKD is more prevalent in older adults and also the greatest increase in dialysis treatment is in the groups aged 65 and over in Australia [42], further research focussing on the barriers and facilitators of using mHealth in both the dialysis and non-dialysis groups are needed.

Conclusion

Mobile phone ownership is high across age, education and socioeconomic status in Australia. Simple one-way SMS messages are likely to reach and be read by those with CKD and therefore would be useful for short, simple reminders to support self-management. Younger people, particularly with earlier stages of CKD, would benefit from more complex mHealth strategies that focus of primary prevention or to improve adherence with treatment. This study also offers a cautionary note as this patient population is not homogenous with respect to mHealth literacy and a one size fits all (or most) approach is unlikely to work. Thorough assessment of technology literacy by renal teams before deciding on education formats is advisable. There is still a vital role for face-to-face education and support for CKD patients. Further research of interactive mHealth support strategies, developed with both technology and health literacies in mind could increase the adoption by a wider group of patients.

Additional file

Additional file 1: Telehealth survey instrument. (PDF 162 kb)

Abbreviation

ATSI: Aboriginal or Torres Strait Islander; CI: Confidence interval; CKD: Chronic kidney disease; ESKD: End-stage kidney disease; mHealth: Internet and mobile phone technologies; non-ATSI: Not aboriginal or Torres Strait Islander; OR: Odds ratio; SMS: Short message service

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Availability of data and materials

The datasets generated and/or analysed during the current study are not publicly available due ethical restrictions by the authorising HRECs.

Authors' contributions

AB and KC conceived and designed the study. KC-W, BHs, BHy and JK were responsible for data collection at their respective sites. JK, KC-W and KG performed data entry and analysis. AB, KG and KH contributed to the interpretation of data. AB, KG and KC-W drafted the manuscript. All authors read and approved the final manuscript.

Ethics approval and consent to participate

Prior to undertaking the study, ethical approval was obtained for each study site via the Metro South Human Research Ethics Committee (HREC/15/QPAH/19), and also from the Queensland University of Technology (1500000370). Participants were advised that the questionnaire was anonymous and that completing the questionnaire would indicate consent.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

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Appendix D: Example consumer feedback on workbook for the ENTICE-CKD program

* Feedback form, or can use back of page to provide your own feedback or write directly on to the workbook if thats easier?

Queensland Health Nutrition Education Materials Online (QH NEMO)
Consumer feedback form

Queensland Government

Name of material under investigation:
Date:

Your feedback is important to us!.
We appreciate your comments, suggestions and opinions of the materials we have developed.

	Good	OK	Poor
Size of typing	[✓]	[ ]	[ ]
Length	[✓]	[ ]	[ ]
Layout	[✓]	[ ]	[ ]
Content	[✓]	[ ]	[ ]
Ease of reading (the words & language used)	[✓]	[ ]	[ ]
Usefulness	[✓]	[ ]	[ ]

Any other comments?

This is a brilliant publication. Answers all questions; psychological help/challenges. Covers everything. Illustrations/information on food something I needed urgently. Section makes one realise there is always more one can do for fitness. CD 76/77 for examples of activity. Congratulations, best wishes with it. I am sure it will be helpful to all patients.

Regards
Maureen Walsham

Thankyou for your time.

D:\Users\conleymar\AppData\Local\Microsoft\Windows\Temporary Internet Files\OLK7791\Consumer_feedback_form (2).DOC

Appendix E: Protein and CKD progression (complementary with Chapter 3)

EDITORIAL

Dietary Sources of Protein and Chronic Kidney Disease Progression: The Proof May Be in the Pattern

Related Article, p. 233

THE MEDIEVAL PHILOSOPHER Moses Maimonides (Spain, 1135-1204) wrote that "*No disease that can be treated by diet should be treated with any other means.*" Not so long ago, before we had the means of dialysis therapy, and still today in many parts of the world, diet represents the sole management strategy in end-stage kidney disease (ESKD).

Arguably, the most common dietary prescription for people with chronic kidney disease (CKD) is a low-protein diet, on the premise it may retard chronic kidney disease (CKD) progression, ameliorate uremia, kidney stone formation, gout, hyperphosphatemia, and gut-derived uremic toxins.[1] However, the effectiveness of low-protein diets have been debated for decades, particularly the paucity and often conflicting evidence underpinning progression to ESKD[2] or all-cause mortality.[3] One potential explanation for the conflicting evidence, which is gaining momentum in the literature, is the discussion of the optimal level and source of dietary protein, specifically the type of animal versus plant-based proteins.[4]

Emerging studies suggest that plant proteins are more protective than animal protein diets in the primary prevention of CKD. A recent analysis of NHANES III participants with reduced estimated glomerular filtration rate (GFR) showed that protein consumption from plant-based sources was associated with significant lower risks of death compared with animal proteins (hazard ratio [HR] 0.85, 95% CI 0.75-0.96; $P = .01$).[5] In the Nurses' Health Study,[6] women with mild CKD consuming a high animal protein diet had significantly greater decline in GFR than women consuming more plant protein (show data). A small clinical study in healthy volunteers initially supported the notion that plant proteins are less harmful than animal proteins, even when matched for total protein intake, and independent of fiber added to the diet.[7] Meta-analysis of high versus normal protein diets demonstrate a diet high in animal protein significantly decreases the GFR in subjects without CKD. Conversely, the authors found insufficient evidence to prove that plant proteins delay the onset of CKD more so than animal proteins.[8]

In this issue of the *Journal*, we are presented with a large longitudinal data set from the Atherosclerosis Risk in Communities Study[9] involving 11,952 US community-dwelling adults free of CKD, diabetes, cardiovascular disease, and heart failure. Sources of dietary protein intake were ascertained from validated food frequency questionnaires grouping protein from unprocessed red meat, processed red meat, red and processed meat intake (combined), poultry, fish and seafood, eggs, high-fat dairy products, low-fat dairy products, nuts, and legumes. During a mean follow-up of 23 years, individuals consuming the highest quartile of vegetable protein had a reduced HR of incident CKD of 24% in a multi-adjusted analysis ($P < .002$). Across all levels of protein intake, there was no significant protection of delaying incident CKD. However, when the analysis targeted individual food groupings, the deleterious effects of red meat proteins on kidney health became more apparent. There were significant increased risks of developing CKD for those who consumed more protein from red and processed meats (HR 1.23; $P < .01$), whereas the CKD risk was lower among those with a higher consumption of low-fat dairy proteins (HR 0.75; $P < .001$), fish and seafood (HR 0.89; $P < .01$), nuts (HR 0.81; $P < .01$), and legumes (HR 0.83; $P < .03$). Haring et al. go a step further in their analysis, showing that if an individual could simply substitute one serving of red and processed meats for one serving per day of the previously mentioned protein sources, the risk of incident CKD would be significantly reduced from 20%, 18%, 14%, and 31%, respectively.

This well-performed epidemiologic analysis complements a previous investigation from the Singapore Chinese Health Study that similarly reported on the deleterious effects of high red meat intake and progression to ESKD in an Asian population.[10] That study suggested that simply substituting one serving of red meat with either one serving of poultry, fish, eggs, or soy/legumes can result in significant declines in ESKD risk, of 62%, 49%, 45%, and 50%, respectively. In comparison, the Asian estimates of these substitution exercises are markedly more pronounced than the analysis from Haring et al., an issue perhaps attributed to the distinctly different habitual dietary pattern in Singapore versus the United States

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(lower consumption of fish and higher consumption of red meat and processed foods).[11,12] In any case, evidence goes in line with a recent meta-analysis concluding that a plant protein–based dietary pattern to significantly reduce the risk of all-cause mortality in individuals with CKD.[13]

Are these associations explained by plant protein *per se*, by the overall dietary pattern that aligns with a higher plant protein intake, or by the healthier lifestyle that presumably accompanies a plant-rich diet?

Animal proteins, in comparison to plant proteins, are of high biologic value (higher proportion of amino acids are absorbed by the gut) and more "complete" in their amino acid profile. They have therefore been historically viewed as superior (in terms of the quality of nutrients provided) to non-animal (plant-based) sources.[4] However, these differences in amino acid composition may render different effects on kidney function. Individuals with high plant protein and low animal protein intake consume greater proportions of cysteine, proline, glycine, alanine and serine, and smaller proportions of the other 13 amino acids versus individuals with lower plant protein and higher animal protein intake. Seminal studies dating back 25 years suggested these differences, particularly in glycine and alanine content, may make protein sources impact differently on kidney damage.[14,15]

Plant proteins are predominantly alkaline inducing, higher in inorganic phosphates (phytates, which have a poor absorption in the intestine), and come from foods that are inherently lower in saturated fat and overall calories (Table 1). A diet with a higher plant-based protein intake was found to be associated with higher bicarbonate levels and improved phosphorous balance in patients with non-dialysis CKD.[16] Clinical investigations support this association, finding that higher intake of fruits and vegetables reduces the renal acid load, blood pressure, and overall body weight in people with established CKD.[17] Diets rich in plant-based proteins have also been found to decrease serum creatinine, C-reactive protein, and proteinuria in CKD,[18-20] which in addition, when paired to higher fiber intake, is associated with reduced nephro-vascular uremic toxin production.[21] In a crossover trial in 9 patients with non-dialysis CKD, 1 week of a predominantly plant protein diet prepared by clinical research staff, equivalent in nutrients to a meat-based diet led to decreased serum phosphorus and fibroblast growth factor 23 levels.[10]

Nonetheless, a person consuming a diet rich in plant protein is perhaps more aware of healthy eating or a healthy lifestyle, and these are residual confounding factors that make drawing conclusions from epidemiology in this area challenging. In fact, the benefits of consuming a plant-rich dietary pattern probably go beyond source of protein and could be attributed to the overall foods and nutrients consumed together[22] (Table 1). Further differences in diets

Table 1. Key Differences in the Nutrition Profile of Plant and Animal Proteins

	Plant Protein	Animal Protein
Calories	Low	High
Essential amino acids	Not complete – exception is quinoa. *Simple meal planning allows patients to complete the essential amino acid profile*	Complete
Saturated fat	Low	High
Unsaturated fat	High	Low
Fiber	High	Low
Iron	Non-haem iron*,† *Present in beans, spinach, raisins, cashews, oatmeal, cabbage, tomato juice*	Haem iron Highly bioavailable
Sodium	Low	High
Potassium	High Low potassium options if required	Low
Phosphate	Low* Lower phosphate-protein ratio	High Higher phosphate-protein ratio
Uremic toxins	Low Harbors saccharolytic bacteria	High Harbors proteolytic bacteria
Antioxidants	High	Low
B_{12}	Low *Present in brown bread, muesli, pickled cucumber, sauerkraut*	High
Calcium	Low* *Present in tofu, mustard and turnip greens, bok choy, kale, spinach*	High in dairy foods
Folate	High	Low
Magnesium	High	Low *Meat and fish are sources of magnesium*
Zinc	Low* *Present in wholegrain breads, cereals, oats, brown rice, nuts, seeds, legumes, tofu, soy, fortified breakfast cereals*	High

*Higher intake of phytic acid in plant protein diets can decrease absorption.
†Vitamin C foods increase absorption.

with a plant-based intake also include a higher intake of fruit and vegetables (with vitamins and antioxidants),[23] fish and omega-3 fatty acids,[24] legumes, wholegrain cereals and nuts,[25,26] and at the same time a lower consumption of sodium,[27] red meat,[28] saturated fats,[29] and common phosphate additives.[30] At the end of the day, this evidence is in keeping with the dietary advice given in healthy eating guidelines to the general population[4] and may give rationale to public health strategies for primary CKD prevention. Although it is a tempting argument, based on these emerging data, that the CKD diet should be more liberalized to "allow" for these higher plant-based intakes, we must bear in mind that observational analyses in population samplings with low estimated GFR may not necessarily extrapolate to referred patients undergoing dietary management with CKD. Observational and interventional studies are required in these referred and managed patients in order to test the hypothesis of the beneficial effects of liberalized diets in the context of the delicate equilibrium of phosphate and potassium intake.[31]

To conclude, the exciting article of Haring et al.[9] suggests that we should consider the differences between protein sources in retarding CKD progression. Because plant protein is not consumed in isolation, the way of implementing these observations into clinical practice is by targeting changes in the overall pattern of eating. Adopting a patient-centered educational approach which shifts focus onto foods, such as wholegrains, fruits, vegetables, as well as proteins from poultry and seafood, rather than "protein" per se, may be of benefit for both the translation of the message and also for disease management. This article furthers our understanding on how substituting foods rather than nutrients affect clinical outcomes for CKD patients. We hope this article encourages these discussions and may lead to future intervention studies to test this impeding question: can a plant-based dietary pattern matched for protein be more effective in retarding CKD progression that a low-protein diet alone?

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Appendix F: CKD.QLD study (complementary with Chapter 4)

ORIGINAL RESEARCH

CPE Dietary Patterns and Clinical Outcomes in Chronic Kidney Disease: The CKD.QLD Nutrition Study

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Objective: Emerging evidence suggests that dietary patterns are associated with survival in people with chronic kidney disease (CKD). This study evaluated the relationship between dietary habits and renal-related clinical outcomes in an established CKD cohort.
Design: Prospective cohort study.
Setting: Three outpatient nephrology clinics in Queensland, Australia.
Subjects: A total of 145 adult patients with Stage 3 or 4 CKD (estimated glomerular filtration rate 15-59 mL/minute/1.73 m^2).
Intervention: Dietary intake was measured using 24-hour recall and the HeartWise Dietary Habits Questionnaire (DHQ), which evaluates 10 components of dietary patterns in relation to cooking habits and intake of food groups.
Main Outcome Measure: The primary outcome was a composite end point of all-cause mortality, commencement of dialysis, and doubling of serum creatinine. Secondary outcome was all-cause mortality alone. Multivariate cox regression analyses calculated hazard ratios (HRs) for associations between DHQ domains and occurrence of composite outcome and adjusted for confounders, including comorbidities and renal function.
Results: Over a median follow-up of 36 months, 32% (n = 47) reached the composite end point, of which 21% died (n = 30). Increasing DHQ score was associated with a lower risk of the composite end point with increasing intake of fruits and vegetables (HR: 0.61; 95% CI, 0.39-0.94) and limiting alcohol consumption (HR, 0.79; 95% CI: 0.65-0.96). For the secondary outcome of all-cause mortality, there was a significant association with adequate intake of fruits and vegetables (HR: 0.35; 95% CI, 0.15-0.83).
Conclusion: Healthy dietary patterns consisting of adequate fruits and vegetables and limited alcohol consumption are associated with a delay in CKD progression and improved survival in patients with Stage 3 or 4 CKD.

This article has an online CPE activity available at www.kidney.org/professionals/CRN/ceuMain.cfm

Introduction

CHRONIC KIDNEY DISEASE (CKD) is a major public health issue,[1] with a worldwide prevalence of approximately 10%–15% in the adult population.[2-5] CKD is associated with poor quality of life, adverse clinical outcomes, and high health care costs.[6,7] There is growing demand for effective and low-cost interventions to tackle this serious health burden.

Current evidence-based guidelines recommend dietary intervention targeting single nutrients, such as sodium, protein, potassium, and phosphorus, to manage CKD and associated cardiovascular risk factors.[8-10] However, single-nutrient interventions have been examined in CKD and demonstrated small, but largely inconclusive effects on CKD outcomes and cardiovascular risk.[11-14] As patients with earlier stages of CKD view dietary interventions as an essential approach to preventing disease progression,[6] research into the optimal dietary intervention that these populations should follow to protect residual kidney function and mitigate cardiovascular disease risk is needed.

Although dietary interventions are considered paramount in CKD management, there are limited and conflicting studies examining the association between dietary patterns and renal-related clinical outcomes in CKD populations.[15-20] Dietary patterns, such as plant-based diet and Mediterranean diet, have been associated with survival.[15-17] In contrast, other studies have shown no such associations.[18-20] An important caveat to each of these studies is they were based on subgroup analyses of subjects

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with renal impairment (typically estimated glomerular filtration rate [eGFR] <60) from largely "healthy" cohort studies or randomized controlled trials in nonrenal populations.[16-20] Therefore, there is a need to establish the association between dietary patterns and outcome in a referred population seeking treatment for CKD.

Therefore, the aim of this prospective cohort study is to investigate the associations between dietary patterns and diet-related habits with the incidence of renal-related end points in patients with Stage 3 or 4 CKD.

Methods

Study Population

The study included adult patients, aged ≥ 18 years, with Stage 3 or 4 CKD (defined as an eGFR between 15 and 59 mL/minute/1.73 m^2) referred to 1 of 3 nephrology outpatient units in Queensland, Australia, between January 1, 2011 and December 31, 2012. Any patients who were unable to provide informed consent or participate in accurately reporting dietary information because of cognitive or other impairments were excluded from the study. Ethics was approved by Metro South Health Service District Human Research Ethics Committee.

Dietary Assessment

Information was collected by trained dietitians who obtained data during routine outpatient appointments, as per the Evidence-based Guidelines for Nutritional Management of CKD.[21] At baseline, dietitians recorded dietary data using the HeartWise Dietary Habits Questionnaire (DHQ) and multiple-pass 24-hour recall method,[22,23] which is a validated dietary assessment tool in the cardiac (non-CKD) rehabilitation population. The DHQ was chosen as it is validated to measure dietary fat, fiber, and sodium intake, which are proxy markers for CKD progression risk factors, and is also a tool that quickly assesses dietary habits and can identify priorities for individual dietary education. The DHQ captures responses of usual intake from a week to over the past month. Dietary patterns and habits were identified across 22 items covering 10 dietary categories, specifically intake of whole grains, fruits, and vegetables, omega-3 fatty acid intake, food preparation methods, food choices, takeaway snacks, sources of dietary fat intake, fiber intake, sodium intake, and alcohol consumption. The score for each category ranges from 1 to 5 with a rating of 1 demonstrating poor habits and a rating of 5 healthy dietary habits.[23]

Data Collection

Participant characteristics of age, gender, nationality, social history (living arrangements, cooking, shopping, and employment), comorbidities, and previous diet interventions were recorded at baseline. Comorbidities were defined according to the Australia and New Zealand Dialysis and Transplant Registry (ANZDATA) registry.[24] Although C-reactive protein was recorded along with the patient's full laboratory results, it was only available in 8% of patients; hence, this was not reported or investigated as potential confounder.

Clinical Outcome

Outcomes for participants were monitored for up to 4 years. The primary outcome was a composite outcome of renal endpoints: all-cause mortality, commencement of dialysis, and doubling of serum creatinine (from the baseline measure). The secondary outcome of interest was all-cause mortality, which was ascertained by linking cohort data to the Registrar General Death data. Commencement of dialysis was assessed via linkage with the ANZDATA. Serum creatinine level was obtained from the latest biochemistry laboratory results, through until November 30, 2014. Any patients who were lost to follow-up in the database were cross-referenced with the ANZDATA for outcome data.

Statistical Analysis

Descriptive statistics were used to examine baseline characteristics. Cox regression analyses were used to examine associations between DHQ scores of each domain (categorical and total DHQ score) and occurrence of composite primary outcome (all-cause mortality, commencement of dialysis, or doubling of serum creatinine). The relationships were expressed as hazard ratios (HRs) and 95% confidence intervals (CIs). In the categorical cox models, dietary domains were analyzed as those with a high DHQ score (≥3), with the low DHQ score (<3) serving as the referent group. Based on previous studies in the area,[17] model 1 adjustments were made for age, gender, smoking status, and eGFR. In model 2, adjustments were made for model 1 plus malnutrition status (subjective global assessment), body mass index, diabetes, and number of comorbidities. Preliminary analyses were also done to decide if parameters were to be adjusted in each model. Proportional hazards assumptions were checked by Schoenfeld residuals. A 2-sided $P < .05$ was considered statistically significant. All analyses were performed with SPSS Statistics (version 23; SPSS Inc., Chicago, IL).

Results

Participants Characteristics

Of 156 consecutive patients approached, 145 participants were consented and included in the analyses (93% consent rate). The percentage of patients who had Stage 3 CKD was 58%, and 41% had Stage 4 CKD. Mean age was 71 ± 12 years, 59% were men, 54% had diabetes, mean eGFR was 32 ± 12 ml/minute/1.73 m^2, and mean systolic blood pressure was 136 ± 20 mm Hg. Baseline characteristics by DHQ score are provided in Table 1. Those who had a high DHQ score had higher eGFR, were more likely to be on cholesterol lowering medications and less likely to smoke (Table 1). Figure 1 illustrates the flow of participants through the study.

Table 1. Baseline Characteristics Classified by Low and High DHQ Scores*

Characteristic	Low DHQ Score (n = 52)	High DHQ Score (n = 86)	*P* Value
Age (y)	72 ± 12	73 ± 10	.24
Male gender (n, %)	30 (57.7)	53 (61.6)	.65
Social factors (n, %)			
Cooking (self)	26 (61.9)	39 (58.2)	.70
Shopping (self)	24 (63.2)	39 (56.5)	.50
Employed	9 (17.6)	11 (12.9)	.45
BMI (kg/m^2)	29 ± 6	31 ± 7	.28
Current smoker (n, %)	7 (15.9)	4 (4.8)	.03
SGA score A (n, %)	46 (88.5)	75 (88.2)	.97
eGFR (ml/min/1.73 m^2)	30 ± 14	35 ± 11	.02
No. of comorbidities ≥ 4 (n, %)†	19 (36.5)	37 (43)	.76
Diabetes (n, %)	22 (42.3)	52 (60.4)	.08
Hypertension (n, %)	37 (71.2)	66 (76.7)	.47
CVD (n, %)	15 (28.8)	24 (27.9)	.90
Systolic blood pressure (mm Hg)	135 ± 21	136 ± 19	.77
Energy intake (kcal/kg/d)	23 ± 27	22 ± 30	.28
Protein intake (g/kg/d)	1.1 ± 0.3	1.1 ± 0.4	.83
Statin use (n, %)	26 (50.0)	60 (69.8)	.02

BMI, body mass index; CVD, cardiovascular disease; DHQ, Heart-Wise Dietary Habits Questionnaire; DM, diabetes mellitus; eGFR, estimated glomerular filtration rate; SGA, subjective global assessment.

Values for categorical variables are given as number (percentage); values for continuous variable are given as mean ± standard deviation.

*Low DHQ score (<3) and high DHQ score (≥3).

†Comorbidities include cardiovascular (myocardial infarction, use of warfarin, congestive heart failure, and hypertension), diabetes (DM 1, DM 2, diabetes nephropathy, and diabetes retinopathy), cancer (metastatic cancer, any tumor, leukemia, and lymphoma), other (mild liver disease, moderate/severe liver disease, peptic liver disease, peripheral vascular disease, depression, connective tissue disease, AIDS, hemiplegia, and skin ulcers/cellulitis).

Dietary Patterns and Composite Primary Outcome

During a median follow-up of 36 months, 32% subjects (n = 47) reached the composite clinical end point, of which 21% died (n = 30), 8% (n = 12) commenced dialysis, and 3% (n = 5) experienced a doubling serum creatinine.

Based on both categorical (adequate intake cut-off of score ≥ 3) and continuous (increasing total DHQ score) predictors, the risk of the composite primary outcome was significantly lower in 8 of 10 domains of the DHQ with adequate and/or increasing intake of whole grains, fruits, and vegetables, fiber, healthier sources of dietary fat, limiting sodium intake, healthier food preparation methods, limiting take-away snacks, and limiting alcohol consumption (Table 2).

There were lower risks of reaching the composite clinical outcome with increasing DHQ scores across for whole grains, fruits, and vegetables, fiber, healthier food preparation methods, limiting take-away snacks, and alcohol consumption (Table 2). The relationship however was only significant for adequate intake of fruits and vegetables (HR model 2, 0.38; 95% CI, 0.18-0.82) after adjustment for confounders.

For every 1-point increase in DHQ score, there was a significantly lower risk of composite clinical outcome with increasing intake of fruits and vegetables (HR model 2, 0.61; 95% CI, 0.39-0.94) and limiting alcohol consumption (HR model 2, 0.79; 95% CI, 0.65-0.96; Fig. 2). The association was no longer significant after adjustment for confounders for increasing intake of whole grains, increasing intake of fiber, healthier food preparation methods, and limitation of take-away snacks (Table 2).

Dietary Patterns and All-Cause Mortality

Over a median follow-up period of 32 months, 30 subjects died (21%). Survival rates were higher for those who had an adequate intake of fruits and vegetables (high DHQ (≥3), HR model 2, 0.35; 95% CI, 0.15-0.83; Fig. 3). The relationship with consumption of healthier sources of dietary fat, limiting sodium intake, and limiting alcohol consumption was no longer significant after adjusting for confounders (Table 2). Associations of each domain of the DHQ to commencing dialysis and doubling serum creatinine were also explored; however, there was no significant relationship (data not shown).

Discussion

This study has shown that a dietary pattern with adequate intake of fruits and vegetables and limited alcohol consumption is associated with lower risk of a composite outcome of all-cause mortality, commencement of dialysis, or doubling of serum creatinine in Stages 3 and 4 CKD patients. Consuming an adequate amount of fruits and vegetables was also the only domain that demonstrated significance for all-cause mortality alone, with a diet higher in fruits and vegetables associated with a 65% reduced risk of all-cause mortality.

These results are in agreement with prior post-hoc analyses demonstrating an association between healthy dietary patterns and clinical outcomes including mortality in persons with and without established CKD.[15-17,25] The National Institutes of Health-American Association of Retired Person Diet and Health Study reported an association between healthy dietary patterns (according to diet quality index scores) and lowered risk of major renal composite outcome of death due to renal cause and initiation of dialysis.[25] The Uppsala Longitudinal Study of Adult Men similarly showed that greater adherence to the Mediterranean diet, a predominantly plant-based diet, was associated with higher survival rates in those with established CKD.[16] Another study showed CKD individuals from the Reasons for Geographic and Racial Differences in Stroke cohort,[17] who consumed a higher proportion of protein from plant-based

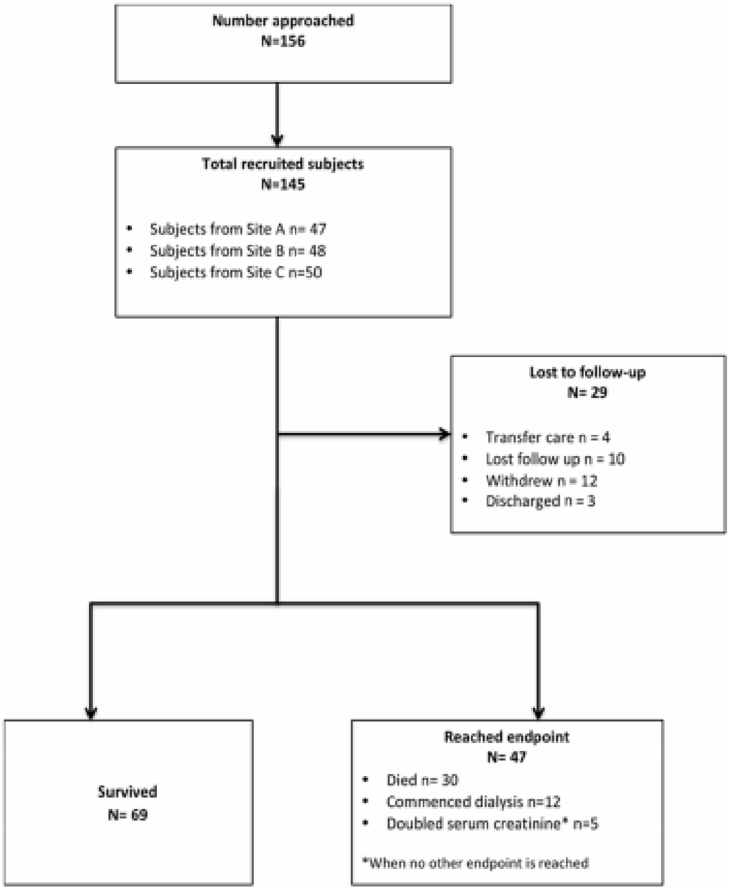

Figure 1. Flow diagram indicating pathways of outcomes of sample.

sources, characterized by high intake of fruits and vegetables, experienced a 23% reduced risk of death.[17] This type of dietary pattern was also shown to be associated with a 33% lower risk of mortality in a sub-population with established CKD from the Third National Health and Nutrition Examination Survey.[15]

One potential mechanism for this association may be the individual protective effect of fruits and vegetables on cardiovascular disease[26] and reduced risk of hypertension with limited alcohol consumption.[27] Other mechanisms explaining the positive effects of fruits and vegetables intake have been widely investigated in previous studies, including the ability to lower blood pressure,[28–32] control weight,[32–35] reduce the risk of diabetes,[36] and improve glycemic control.[37] One randomized controlled trial and 1 cross-sectional study have suggested higher intakes of fruits and vegetables may delay kidney function decline by reducing inflammation and improving acid–base balance.[38,39] Studies have also demonstrated that diets higher in fruits, vegetables, whole grains, and low-fat dairy foods may be protective against eGFR decline and associated with lower urinary albumin-to-creatinine ratio and lower albumin excretion rate.[38,39] The antioxidant properties and fiber content of fruits and vegetables may have protective effects on inflammation markers, such as C-reactive protein and soluble intercellular adhesion molecule-1,[40] and explain the relationship with albuminuria and inflammation.[41,42] It was also suggested that the beneficial effect of proteins from plant-based foods was suggested to be favorable because of its effects on cholesterol metabolism,[43] decreased production of uremic toxins,[44] and its protective effect on albumin leakage over animal-based protein diets.[38,45]

In this study, no association was observed between the other DHQ domains (adequate intake of whole grains, fiber, healthier sources of dietary fat intake, omega-3 fatty acid, using ideal food preparation methods, better food choices, limiting take-away snacks, and limiting sodium intake) and primary and secondary outcomes. This may

Table 2. Association of Dietary Habits Questionnaire Domains With Composite Clinical Outcome and All-Cause Mortality in a Cohort of Chronic Kidney Disease Patients (n = 145)

	Composite Clinical Outcome[a]		All-Cause Mortality	
Characteristic	High DHQ Score (≥3) (95% CI)	Every 1-Point Increase in DHQ Score (95% CI)	High DHQ Score (≥3) (95% CI)	Every 1-Point Increase in DHQ Score (95% CI)
Increasing whole grains				
HR	0.49 (0.26-0.91)*	0.73 (0.55-0.97)*	0.64 (0.32-1.27)	0.86 (0.64-1.17)
HR model 1	0.74 (0.35-1.55)	0.86 (0.61-1.21)	0.60 (0.25-1.30)	0.85 (0.59-1.23)
HR model 2	0.77 (0.35-1.69)	0.83 (0.58-1.18)	0.58 (0.24-1.41)	0.87 (0.60-1.26)
Increasing fruits and vegetables				
HR	0.33 (0.17-0.63)*	0.54 (0.38-0.76)*	0.32 (0.16-0.68)*	0.67 (0.48-0.95)*
HR model 1	0.49 (0.24-1.03)	0.67 (0.44-1.01)*	0.43 (0.19-1.01)	0.80 (0.53-1.21)
HR model 2	0.38 (0.18-0.82)*	0.61 (0.39-0.94)*	0.35 (0.15-0.83)*	0.76 (0.49-1.18)
Healthier sources of dietary fat				
HR	0.53 (0.25-1.09)	0.73 (0.43-1.25)	0.41 (0.19-0.89)*	0.49 (0.28-0.89)*
HR model 1	0.66 (0.25-1.78)	1.00 (0.54-1.87)	1.23 (0.36-4.25)	0.81 (0.40-1.63)
HR model 2	0.46 (0.15-1.40)	0.84 (0.43-1.64)	1.07 (0.23-5.06)	0.74 (0.33-1.66)
Limiting sodium intake				
HR	0.68 (0.37-1.25)	0.82 (0.57-1.19)	0.49 (0.25-0.97)*	0.65 (0.44-0.95)*
HR model 1	0.87 (0.42-1.79)	0.99 (0.64-1.53)	0.76 (0.33-1.72)	0.90 (0.56-1.44)
HR model 2	0.80 (0.39-1.66)	0.85 (0.52-1.39)	0.74 (0.32-1.71)	0.58 (0.50-1.47)
Increasing fiber intake				
HR	0.55 (0.30-1.01)	0.60 (0.43-0.85)*	0.53 (0.27-1.06)	0.75 (0.53-1.07)
HR model 1	1.05 (0.52-2.11)	0.79 (0.51-1.21)	0.80 (0.35-1.79)	0.85 (0.55-1.31)
HR model 2	0.90 (0.43-1.88)	0.71 (0.45-1.12)	0.75 (0.31-1.85)	0.82 (0.52-1.29)
Omega-3 fatty acid intake				
HR	1.33 (0.71-2.49)	1.11 (0.83-1.47)	1.70 (0.87-3.34)	1.26 (0.93-1.72)
HR model 1	1.55 (0.77-3.09)	1.18 (0.85-1.64)	1.80 (0.84-3.86)	1.42 (0.99-2.01)
HR model 2	1.21 (0.57-2.56)	1.06 (0.74-1.52)	1.59 (0.70-3.58)	1.35 (0.92-1.97)
Food choice including quality of fat intake†				
HR	0.62 (0.32-1.20)	1.03 (0.76-1.39)	0.68 (0.33-1.41)	0.80 (0.59-1.09)
HR model 1	0.83 (0.40-1.73)	1.13 (0.81-1.57)	1.29 (0.55-2.99)	0.93 (0.65-1.33)
HR model 2	0.70 (0.32-1.53)	1.06 (0.74-1.51)	1.30 (0.52-3.27)	0.97 (0.66-1.42)
Healthier food preparation methods				
HR	0.63 (0.32-1.25)	0.72 (0.56-0.93)*	0.71 (0.33-1.52)	0.90 (0.69-1.18)
HR model 1	0.66 (0.26-1.16)	0.77 (0.55-1.05)	0.88 (0.32-2.42)	0.96 (0.67-1.37)
HR model 2	0.59 (0.22-1.54)	0.75 (0.54-1.04)	0.61 (0.22-1.71)	0.86 (0.61-1.22)
Limiting take-away snacks				
HR	0.44 (0.23-0.82)*	0.73 (0.56-0.95)*	0.60 (0.30-1.22)	0.89 (0.69-1.17)
HR model 1	0.67 (0.33-1.36)	0.86 (0.64-1.16)	0.87 (0.39-1.96)	1.02 (0.75-1.40)
HR model 2	0.60 (0.28-1.32)	0.78 (0.57-1.06)	1.07 (0.41-2.76)	0.95 (0.69-1.30)
Limiting alcohol consumption				
HR	0.33 (0.13-0.81)*	0.82 (0.72-0.95)*	0.38 (0.14-0.99)*	0.91 (0.78-1.07)
HR model 1	0.44 (0.14-1.33)	0.81 (0.69-0.96)*	0.66 (0.20-2.15)	0.99 (0.81-1.21)
HR model 2	1.67 (0.36-7.72)	0.79 (0.65-0.96)*	2.08 (0.25-17.56)	0.97 (0.78-1.23)

CI, confidence interval; DHQ, HeartWise Dietary Habits Questionnaire; HR, hazard ratio.

Model 1 is adjusted for age, gender, and eGFR. Model 2 is adjusted for variables in Model 1 and body mass index, malnutrition status (subjective global assessment), diabetes, and number of comorbidities. HR of high DHQ score is compared with low DHQ score; low DHQ score is used as the reference category.

[a]Refers to death, commencement of dialysis, or doubling of serum creatinine.

*Result is significant as P value ≤ .05.

†Food choice assesses the quality of fat intake in an individual's diet through frequency intake of low fat versus regular fat products intake of fish, processed meat, and type of spread consumed.

have been because of several reasons. First, given the relatively modest number of participants and events, there is a possibility that the analysis was underpowered to detect significant associations between the dietary domains and mortality. Second, the DHQ assessment was self-reported, which may have resulted in reporting errors because of reduced accuracy of dietary measurement, inability to remember, underestimating or overestimating amount eaten and portion sizes, and social desirability bias.[46]

It is recognized that a diet with reduced sodium is a component of a dietary pattern that may lower the risk of cardiovascular events and all-cause mortality.[11,47-50] This relationship is suggested to be mediated by positive effects on blood pressure[51] and lipid profiles.[50] In contrast, this study

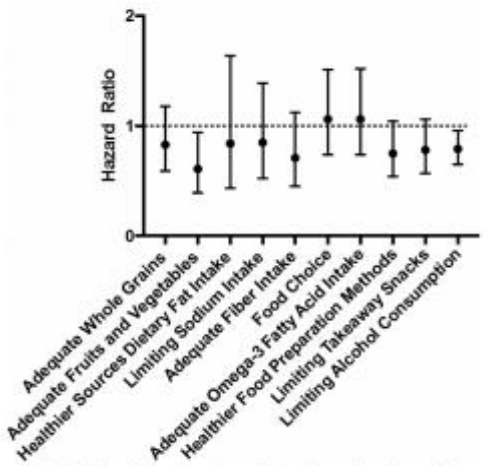

Figure 2. Risk of composite clinical end point with every 1-point increase in DHQ score stratified by dietary domains of the DHQ in a cohort of CKD patients (n = 145). This figure represents adjusted model 2 that was adjusted for age, gender, eGFR, SGA, BMI, diabetes, and number of comorbidities. Error bars represent 95% confidence intervals. BMI, body mass index; CKD, chronic kidney disease; DHQ, HeartWise Dietary Habits Questionnaire; eGFR, estimated glomerular filtration rate; SGA, subjective global assessment.

did not find an association between these dietary pattern components and adverse events. This may be because of the way sodium intake was captured on the DHQ. Intake of processed meats, pastries, and take-away style foods are not attributed to overall sodium intake in the DHQ scoring domain, which some suggest is a substantial source of total sodium intake in the modern food supply.[52]

To the investigators' knowledge, this study is the first cohort study in an established CKD population to test the association of dietary patterns and clinical outcomes. A significant association was observed between consuming adequate fruits and vegetables and the composite outcome of mortality, doubling of serum creatinine and initiating dialysis, and all-cause mortality alone. A dietary pattern with adequate intake of whole grains was also associated with a reduction in the risk of composite outcome by 27%. This was in agreement with a recent systematic review that reported a 27% lower risk of death associated with healthy eating patterns characterized by higher intakes of fruits and vegetables, fish, legumes, cereals, and whole grains, and lower intakes of red meat, salt, and refined sugars.[53]

Despite these strengths, this study does have important limitations worth noting. First, the sample size was relatively small (n = 145), and participants were only monitored for 48 months, such that the possibility of a type 2 statistical error cannot be excluded. Nonetheless, robust associations between important DHQ diet domains suggest that the study was adequately powered for the predictor of fruit and vegetable intake. Second, the DHQ consisted of 10 domains, which resulted in testing of multiple exposures, which may increase the risk of type 1 error. However, the findings were consistent with other prospective studies in this population.

In conclusion, the present study shows that consuming a dietary pattern characterized by adequate intake fruits and vegetables and limited alcohol consumption is associated

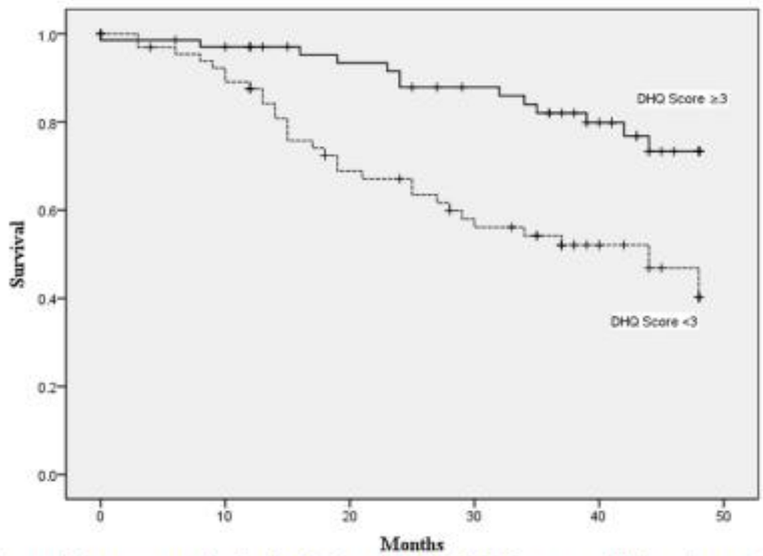

Figure 3. Kaplan–Meier survival curves stratified by low (<3) and high (≥3) DHQ scores of fruit and vegetable intake in a cohort of CKD patients (n = 145). CKD, chronic kidney disease; DHQ, HeartWise Dietary Habits Questionnaire.

with a lower risk of the composite outcome of death, commencement of dialysis, or doubled serum creatinine levels. In current clinical practice, there can be a focus on restriction of fruits and vegetables because of concerns of higher dietary potassium and/or phosphate consumption with kidney dysfunction.[54] As single nutrient-focused diets are not typically reflective of a regular diet, our study reinforces the significance of an overall healthy diet, rather than confined focus on certain foods or single nutrients. The synergy between food and nutrients altogether may result in greater health benefits than each food component alone. This finding suggests a shift to focus on healthful dietary pattern with an intake of ≥6 pieces of fruits per week and ≥3 serves of vegetables per day is associated with a reduction in major renal outcomes in those with early or moderate stages of CKD. Intervention studies are needed to establish whether improving dietary patterns results can impact on major renal outcomes.

Practical Application

This study adds to the growing momentum of evidence supporting the positive effects of plant-based dietary patterns and also encourages a shift in focus from single nutrient interventions to overall healthy diet interventions for CKD management. Dietary advice based on a whole food approach, encouraging increased fruit and vegetable intakes, could be an effective tool to reduce mortality in people with kidney disease.

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Appendix G: Chapter 4 search terms

Database searched	Search terms
Medline	Kidney Diseases/
	Diabetic Nephropathies/
	exp Renal Replacement Therapy/
	Renal Insufficiency/
	exp Renal Insufficiency, Chronic/
	dialysis.tw.
	(hemodialysis or haemodialysis).tw.
	(hemofiltration or haemofiltration).tw.
	(hemodiafiltration or haemodiafiltration).tw.
	(kidney disease or renal disease or kidney failure or renal failure).tw.
	(ESRF or ESKF or ESRD or ESKD).tw.
	(CKF or CKD or CRF or CRD).tw.
	(CAPD or CCPD or APD).tw.
	(predialysis or pre-dialysis).tw.
	(kidney transplant* or renal transplant* or kidney graft* or renal graft*).tw.
	diabetic nephropath*.tw.
	exp Proteinuria/
	Glomerular Filtration Rate/
	proteinuria.tw.
	albuminuria.tw.
	(glomerular filtration rate or GFR or eGFR).tw.
	or/1-21
	exp Diet/
	Diet Therapy/
	exp Food Habits/
	Fruit/ and Vegetables/
	((diet or diets or dietary or nutrition*) adj2 (pattern* or quality or guideline*)).tw.
	((diet or diets or dietary) adj5 (Mediterranean or vegetarian or plant-based or American Heart Association* or DASH or western or seafood)).tw.
	((diet or diets or dietary or high or increase* or rich) adj5 (fruit* or vegetable* or nut or nuts or fibre or fiber or olive oil or omega-3 fatty acids or unsaturated or polyunsaturated or monounsaturated or fish or seafood pulses)).tw.
	(food adj2 group*).tw.
	healthy eating index.tw.
	((diet or dietary or nutrition*) adj (survey* or record or records or score)).tw.
	food frequency questionnaire*.tw.
	diet.tw.
	or/23-34
	and/22,35
	exp Cohort Studies/
	between group*.tw.

Database searched	Search terms
	risk.mp.
	exp Case-Control Studies/
	((cohort or concurrent or longitudinal or follow-up or followup or prospective or retrospective or cross-sectional or case-control) adj2 (analys* or design* or evaluation* or research or study or studies or survey*)).tw.
	(incidence adj1 (analys* or research or study or studies or survey*)).tw.
	or/37-42
	and/36,43
Embase	exp renal replacement therapy/
	kidney disease/
	chronic kidney disease/
	kidney failure/
	chronic kidney failure/
	mild renal impairment/
	stage 1 kidney disease/
	moderate renal impairment/
	severe renal impairment/
	end stage renal disease/
	renal replacement therapy-dependent renal disease/
	kidney transplantation/
	diabetic nephropathy/
	(hemodialysis or haemodialysis).tw.
	(hemofiltration or haemofiltration).tw.
	(hemodiafiltration or haemodiafiltration).tw.
	(kidney disease* or renal disease* or kidney failure or renal failure).tw.
	(kidney transplant* or renal transplant* or kidney graft* or renal graft*).tw.
	(ESRF or ESKF or ESRD or ESKD).tw.
	(CKF or CKD or CRF or CRD).tw.
	(CAPD or CCPD or APD).tw.
	dialysis.tw.
	predialysis.tw.
	diabetic nephropath*.tw.
	exp Proteinuria/
	glomerulus filtration rate/
	proteinuria.tw.
	albuminuria.tw.
	(glomerular filtration rate or GFR or eGFR).tw.
	or/1-29
	exp diet/
	diabetic diet/
	low fat diet/
	diet therapy/
	dietary intake/
	Fruit/ and Vegetable/

Database searched	Search terms
	((diet or diets or dietary or nutrition*) adj2 (pattern* or quality or guideline*)).tw.
	((diet or diets or dietary) adj5 (Mediterranean or vegetarian or plant-based or American Heart Association* or DASH or western or seafood)).tw.
	((diet or diets or dietary or high or increase* or rich) adj5 (fruit* or vegetable* or nut or nuts or fibre or fiber or olive oil or omega-3 fatty acids or unsaturated or polyunsaturated or monounsaturated or fish or seafood or pulses)).tw.
	(food adj2 group*).tw.
	healthy eating index.tw.
	((diet or dietary or nutrition*) adj (survey* or record or records or score)).tw.
	food frequency questionnaire*.tw.
	diet.tw.
	or/31-44
	and/30,45
	risk*.mp.
	case-control study/
	longitudinal study/
	retrospective study/
	prospective study/
	cohort analysis/
	cross-sectional study/
	cohort analysis/
	health survey/
	incidence/
	between group*.tw.
	((cohort or concurrent or longitudinal or follow-up or followup or prospective or retrospective or cross-sectional or case-control) adj2 (analys* or design* or evaluation* or research or study or studies or survey*)).tw.
	(incidence adj1 (analys* or research or study or studies or survey*)).tw.
	or/47-59
	and/46,60

Appendix H: TIDieR reporting in telehealth-delivered dietary interventions (complementary with Chapter 5)

JOURNAL OF MEDICAL INTERNET RESEARCH Warner et al

Review

Reporting of Telehealth-Delivered Dietary Intervention Trials in Chronic Disease: Systematic Review

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Abstract

Background: Telehealth-delivered dietary interventions are effective for chronic disease management and are an emerging area of clinical practice. However, to apply interventions from the research setting in clinical practice, health professionals need details of each intervention component.

Objective: The aim of this study was to evaluate the completeness of intervention reporting in published dietary chronic disease management trials that used telehealth delivery methods.

Methods: Eligible randomized controlled trial publications were identified through a systematic review. The completeness of reporting of experimental and comparison interventions was assessed by two independent assessors using the Template for Intervention Description and Replication (TIDieR) checklist that consists of 12 items including intervention rationale, materials used, procedures, providers, delivery mode, location, when and how much intervention delivered, intervention tailoring, intervention modifications, and fidelity. Where reporting was incomplete, further information was sought from additional published material and through email correspondence with trial authors.

Results: Within the 37 eligible trials, there were 49 experimental interventions and 37 comparison interventions. One trial reported every TIDieR item for their experimental intervention. No publications reported every item for the comparison intervention. For the experimental interventions, the most commonly reported items were location (96%), mode of delivery (98%), and rationale for the essential intervention elements (96%). Least reported items for experimental interventions were modifications (2%) and intervention material descriptions (39%) and where to access them (20%). Of the 37 authors, 14 responded with further information, and 8 could not be contacted.

Conclusions: Many details of the experimental and comparison interventions in telehealth-delivered dietary chronic disease management trials are incompletely reported. This prevents accurate interpretation of trial results and implementation of effective interventions in clinical practice.

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KEYWORDS
telemedicine; diet; chronic disease; behavior; review

Introduction

Telehealth is an effective mode for delivering dietary interventions [1,2]. There is a strong relationship between dietary quality and the prevention and management of chronic diseases [3] including diabetes [4], cardiovascular disease [5], and obesity [6]. Telehealth-delivered dietary interventions have been shown to significantly improve blood pressure, cholesterol, triglycerides, body weight, and waist circumference in people with chronic diseases [2]. There are a multitude of barriers to face-to-face dietary interventions, including nonattendance to clinics, transport problems, inflexible hours, long wait times, and cost for both the patient and the practitioner [1,2,7]. These barriers can be addressed by adopting telehealth, which has been accepted by participants in dietary behavior change [2,8] and chronic disease management [9-11] studies. Although its use is promising, telehealth is a widely used term, and its emerging use in clinical practice is broad and varied [2,9,10,12-14]. Telehealth methods including mobile health and electronic health, may involve delivery of health care via telephone, SMS text message (short message service, SMS), email, video, website, and other remote devices. These devices can be used for one-on-one consultations, store-and-forward education, behavior change reminders, and remote monitoring and feedback. There remain a number of challenges for introducing telehealth into health care systems, such as inconsistent terminology, evolving telehealth technologies, and limited public and private health funding for implementation into standard care [12]. Developing a strong evidence-base for the use of telehealth will help to better understand how to overcome such challenges.

To implement effective telehealth interventions, practitioners need to know what telehealth is and how it is used. Translating knowledge from trials into clinical practice is crucial for improving health care and chronic disease management. However, this translation is challenged when trials are poorly reported and provide insufficient detail for implementing evidence-based interventions in practice [15-18].

In addition to the complexity of telehealth delivery, dietary behavior change interventions also have many layers of complexity in terms of the number of dietary factors targeted; the need for comprehensive individualized behavior change techniques; interrelated lifestyle behaviors; and the influence of social and environmental circumstances, attitudes, and skill levels [19,20]. Complex nonpharmacological interventions have been recently shown to be poorly reported [21-24]. To our knowledge, no previous studies have examined the reporting of interventions in dietary or telehealth-delivered trials. In addition to the complete reporting of experimental intervention components, it is important that comparison or control interventions are completely described to allow accurate interpretation and evaluation of effect size within and across trials.

This review aimed to evaluate the completeness of intervention reporting of experimental and comparison interventions in published dietary chronic disease management trials that used telehealth delivery methods.

Methods

Study Design

This study is a secondary analysis of the articles identified in a systematic review that examined the effectiveness of telehealth-delivered dietary interventions in chronic disease [2].

Search Strategy

Eligible studies were identified from a systematic review of randomized controlled trials (RCTs) using telehealth methods to deliver multifactorial dietary interventions in adults with chronic disease, conducted by our team [2]. A literature search was performed across multiple electronic databases (MEDLINE, EMBASE, CINAHL, and PsychINFO) up to November 2015, as detailed previously [25]. A multi-step search approach was taken to retrieve relevant trial publications for this study using forward and backward citation searching; expert correspondence; and searching conference abstracts, theses, dissertations, and clinical trial registries to identify ongoing trials. Two researchers (JK and MW) independently screened the search articles, and disagreements were resolved by discussion.

Trial Publication Selection

Trial publications were included in this review if they were RCTs, cluster RCTs, or quasi-RCTs conducted in adults (>18 years of age) with at least one diet-related chronic disease. Experimental interventions were required to include two or more dietary components (eg, vegetables and whole grains). Half of the total intervention contact hours or interaction contacts was required to be delivered by telehealth and must have been developed or delivered by a qualified health professional. This study includes all telehealth-delivered dietary interventions, regardless of reporting of dietary outcomes. Studies analyzed in this study met the inclusion criteria as outlined in the systematic review protocol [25]. The original review included 25 studies with diet outcome data; however, this current reanalysis includes an additional 12 studies without diet outcome data, which otherwise met the inclusion criteria for this review. All 37 studies were therefore analyzed for completeness of reporting of the intervention, regardless of the reporting of outcome data.

Assessment of Trial Reporting

To appraise the completeness of reporting of telehealth-delivered dietary interventions, the Template for Intervention Description and Replication (TIDieR) checklist and guide [18] was used. The 12-item TIDieR checklist is an extension of item 5 of the consolidated standards of reporting trials (CONSORT) 2010 statement [26] and item 11 of the Standard Protocol Items: Recommendations for Interventional Trials checklist [27].

The completeness of reporting of experimental and comparison interventions in each trial was recorded on a data extraction form (Multimedia Appendix 1) based on the TIDieR checklist [18]. If trials had more than one experimental intervention group, the interventions were assessed separately. Two researchers (MW and JK) independently assessed each trial and discussed differences in the rating of TIDieR items. There was an 88% agreement between the two reviewers before the initial discussion. After reappraisal and further discussion, less than 1% of items appraised were conflicting, which were then resolved with discussion to reach a consensus. If consensus could not be achieved, a third researcher (TH) was available to resolve any conflicts.

Procedure for Attaining Additional Intervention Information

Reference lists, clinical trial registration records, available trial protocols, and trial authors' research profiles were screened to determine whether additional written information about each trial's intervention was publicly available. Information obtained from these sources was considered, and checklist items were rescored as *complete from additional sources* where relevant. For items remaining incomplete, attempts were made to contact trial authors by emailing them questions specifically related to the incomplete items for the experimental interventions. Where corresponding author email addresses were unavailable, attempts were made to search for alternate email addresses and contact other authors via email. Authors were sent up to three email reminders, each approximately 3 weeks apart. Author responses were used to rescore the TIDieR checklist.

Data Analysis

Data were analyzed using descriptive statistics (number and percentages) in Excel 2010 (Microsoft).

Results

Characteristics of Included Trials

A total of 37 trials were included (Figure 1) [2], of which 49 were experimental interventions and 37 were comparison interventions. Of the 37 trials, 29 evaluated one experimental intervention [7,8,14,28-53], 4 trials evaluated two experimental interventions [54-57], and 4 trials evaluated three experimental interventions [58-61]. Trials were published from 1981 and 2016 and conducted in patients with cardiovascular disease or heart failure (n=13) [7,8,29,31,36-40,42,56,57,62], hypertension (n=11) [14,32-34,43,44,54-56,59,60], diabetes (n=10) [14,28,30,35,45-50,56,61], kidney disease (n=3) [51,52,58], and obesity (n=3) [32,53,57]. The majority of trials involved face-to-face interaction between intervention providers and participants before the telehealth component of the intervention.

Figure 1. Flow of the trial publication selection and author contact process (blue or dashed boxes represent the steps taken as part of the existing systematic review; green or line boxes were steps taken for this study).

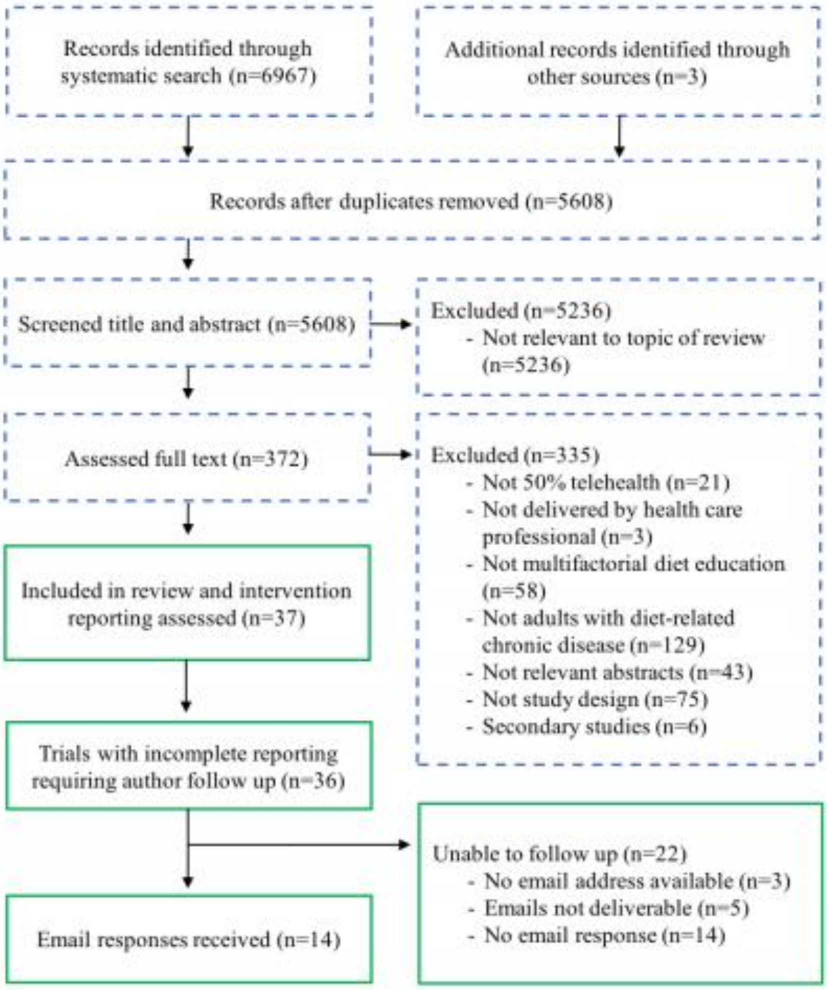
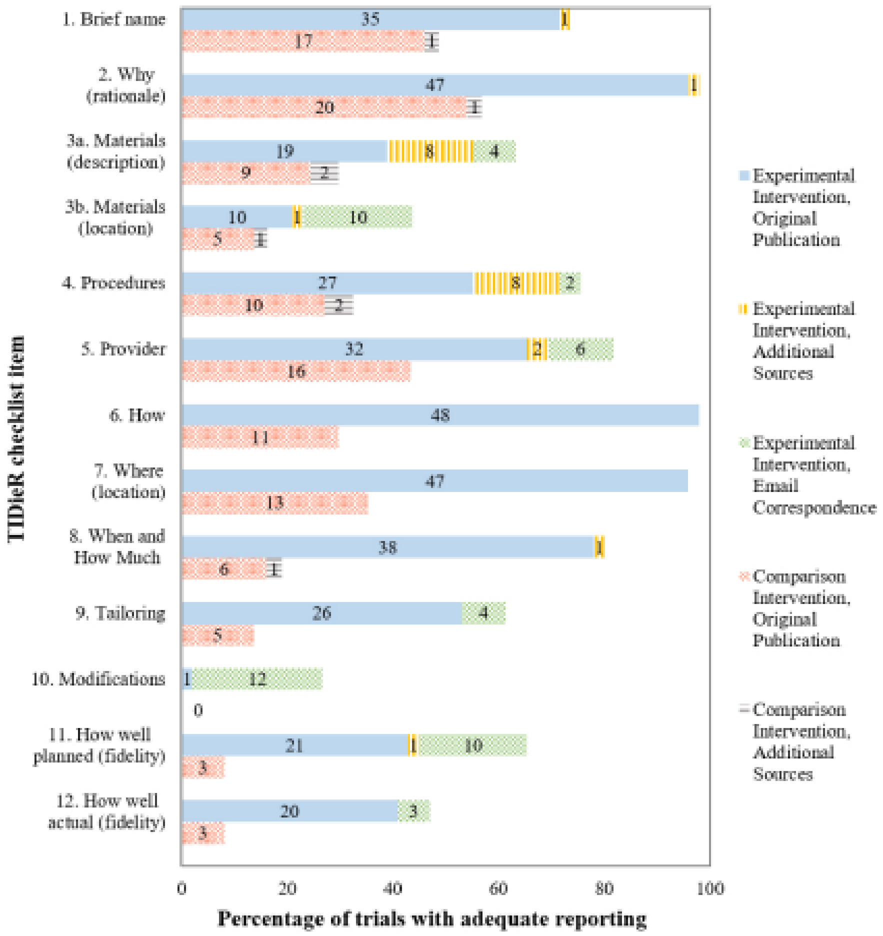


Figure 2. Items with complete reporting across the 12 Template for Intervention Description and Replication (TIDieR) checklist items in 49 experimental and 37 comparison interventions of dietary trials delivered by telehealth. Numbers in bars represent the number of interventions rated as complete.



Most interventions (70%) used the telephone as the telehealth delivery method, others used short message service (SMS), the Internet, video, videoconferencing, and a mix of telehealth methods. Figure 2 shows the percentage and number of experimental and comparison interventions that completely reported each TIDieR checklist item in the original trial publication, in additional sources of published information, and after email correspondence with authors.

Reporting of Experimental Interventions

Nearly all (98%, 48/49) experimental interventions were incompletely reported in their original publication. Only one publication [8] completely reported every checklist item. Items that were commonly reported included how or the mode of delivery (item 6), rationale (item 2), and location (item 7) of the intervention. Items with the poorest reporting were materials (items 3a-b), modifications to the intervention (item 10), and fidelity (items 11-12). Intervention materials such as training materials, questionnaires, handbooks, leaflets, videoconferencing units, short SMS text messages, or websites were used in all trials. Interventions with incomplete reporting of procedures (item 4) commonly missed details required for replicating the dietary advice provided to participants.

Reporting of Comparison Interventions

The majority (78%, 29/37) of comparison interventions were described as "usual care," whereas others (22%, 8/37) were "control interventions" with less intensive procedures (eg, education sessions without telephone or email follow-up, resources, or extra video education). The most commonly reported items were rationale (item 2), brief name (item 1), and provider (item 5). The least reported items were modifications (item 10), fidelity (items 11-12), materials (items 3a-b), tailoring (item 9), and when and how much of the comparison intervention was provided (item 8). More comparison interventions had intervention details incompletely reported than experimental interventions.

Searching Additional Sources and Contacting Authors for Intervention Information

Although descriptions of the materials used in the experimental intervention were poorly reported in the original publications

(39%, 19/49), details were provided in additional sources of information (16%, 8/49) and by contacting authors through email (8%, 4/49). The locations of the materials used in the experimental intervention were further reported in email correspondence with authors (20%, 10/49). Searching additional sources of published information was time-consuming and only satisfied an additional 3% and 2% of checklist items for experimental and comparison interventions, respectively. Likewise, attaining information through email required 40 reminder emails to be sent; only 39% (14/36) of authors replied with further information, and author responses were up to 8 weeks after the initial email.

Discussion

Principal Findings

This study aimed to evaluate the completeness of reporting of experimental and comparison interventions in dietary chronic disease management trials that used telehealth delivery methods. The key finding was that only one experimental intervention (2%) and no comparison interventions were reported in enough detail to satisfy every TIDieR checklist item. This finding illustrates a major deficit in the reporting of information that is required for health professionals to accurately replicate dietary interventions.

Findings from this study are consistent with other evaluations of the completeness of reporting of nonpharmacological interventions that have found poor reporting across trials of physiotherapy, occupational therapy, smoking cessation, and cardiac and stroke rehabilitation interventions [21-23,62-64]. Reporting of the experimental intervention rationale, mode of delivery, and location or setting was complete in most trials, which is consistent with findings of other studies [21-23]. Although details of intervention providers were not well described in the included publications (65%, 32/49 experimental interventions; 43%, 16/37 comparison interventions), we found a greater proportion of complete reporting compared with previous studies; whereby, details on intervention providers were reported in 59% of original cardiac rehabilitation intervention publications [22] and 38% interventions for upper limb therapies in cerebral palsy [23]. Reporting of the delivery mode, location or setting, and provider details may have been inflated in this study because of the restrictive and predefined inclusion criteria for selecting relevant trials.

Accurate interpretation of intervention effects is limited when the dose and frequency of dietary support or education in each of the experimental and comparison interventions is unknown. The amount (dose) of contact, for example, has been shown to be positively associated with sustained dietary behavior change [1]. Reporting of comparison intervention details, including the dose and frequency of intervention delivery, is necessary for accurate interpretation and evaluation of treatment effect size within and across trials.

Most comparison interventions (78%, 29/37) were briefly described as simply "usual care." This is of concern because usual care is likely to differ for participants within and between trials because of a multitude of determinants including the health professional(s) and other personnel involved and the country's health care system [23]. The completeness of reporting of comparison interventions in randomized trials has been explored previously; whereby, less than 40% of publications completely report the procedures, materials used, mode of delivery, tailoring, modifications, and planned and actual fidelity of comparison interventions [23,64]. Comparison interventions should be reported more completely to allow health professionals to make a clinical judgment on the additional benefit of an experimental intervention.

Trial publications with complete descriptions of physical and informational materials allow readers to use the materials of effective interventions in practice. This study found that descriptions of materials (39%, 19/49 experimental interventions) and where to access materials (21%, 10/49 experimental interventions) were poor, which is similar to previous findings [23,64]. If authors are unable to describe the materials completely in the main publication, they need to specify where further information about or the actual information materials can be found so that all elements of effective telehealth interventions can be used in practice.

Multifactorial dietary behavior change trials, regardless of their mode of delivery, are complex in comparison with trials of simple or single interventions. This is partly because of internal and external influencing factors including social and environmental circumstances, attitudes, and skill levels [19,20]. Tailoring chronic disease management strategies to support individualized dietary and lifestyle behavior change is particularly important. Tailoring of experimental interventions to trial participants was reported in only 53% (26/49) of trial publications. Many interventions were *tailored to each individual*, yet few trials reported the rationale, guides, variables, or constructs used for participant assessment, decision points, or actions for tailoring (eg, questionnaire to determine adherence to diet at a specific time point) [18]. Completely describing tailoring is challenging; however, detailed descriptions help readers to distinguish between intentional tailoring and poor fidelity [65]. As consistent taxonomy for behavior change techniques are further developed [16], reporting of tailoring for behavior change interventions will hopefully become more widespread.

Assessing fidelity in dietary behavior change trials is similarly complex in comparison with simple trials [18,65]. Intervention fidelity encompasses aspects such as the intervention design, delivery and receipt, and how well participants are able to use learned skills outside of formal intervention sessions [66]. Reporting of intervention fidelity is required for readers to accurately interpret reliability and validity, as well as optimize the efficacy of future interventions and clinical practice. Similar to findings in this study, fidelity of complex behavior change has previously found to be poorly reported [67]. For example, 87% (146/168) of behavioral pediatric obesity intervention trials reported less than half of assessed fidelity components.

Although word or page limits in peer-reviewed journals may be one of the restrictions perceived by authors as a barrier to fully describing interventions [68], Web-based supplementary materials and publishing of detailed trial protocols may assist in overcoming restrictions [19,23]. The incomplete intervention reporting in our sample of studies may have occurred for a number of reasons including lack of awareness by trial authors about what constitutes a complete intervention description and the importance of it; no requirement to adhere to TIDieR checklist by most journals in which telehealth-delivered dietary trials are published; and publication of studies before release of the TIDieR checklist in 2014, although the CONSORT extension for nonpharmacological interventions was published in 2008 and contains some expanded guidance for reporting interventions.

This study is the first to evaluate the completeness of intervention reporting in trials of dietary intervention delivered by telehealth methods. Strengths of this study include the thorough evaluation by two independent reviewers, of intervention reporting including evaluation of additional sources of published information, and email correspondence with authors. Although the TIDieR checklist is extensive, it does not directly specify all variables that may influence the outcome of the intended intervention, such as personal attributes of the person delivering the intervention. The majority of the included trials involved physical activity and lifestyle components, as well as dietary behavior change components. As the scope of this study was limited to telehealth-delivered dietary interventions, conclusions on the reporting of other telehealth interventions cannot be drawn. This study highlights that trials of complex interventions need to report each component of chronic disease management completely for accurate evaluation and replication of components of the trial, or the trial as a whole.

Conclusions

Intervention details of dietary trials delivered by telehealth methods are not adequately reported, limiting their replication in research and clinical practice. The least reported items of the experimental intervention were descriptions and locations of the physical and informational materials used. Reporting of comparison intervention details needs to be more complete to allow evaluation of the additional benefit of experimental interventions. Inadequate reporting of trials prevents closure of the translational gap between research trials and clinical practice, thereby limiting the potential for health care professionals to implement effective interventions to assist people with managing their chronic disease. Our findings confirm the pressing need for authors, editors, and reviewers to use the TIDieR checklist to ensure complete reporting of published dietetic trials.

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Authors' Contributions

MW assessed included studies, conducted the analysis, drafted the manuscript, and had primary responsibility for final content. JK assisted in the conceptualization of the study, conducted the literature search, assessed the studies, and assisted with manuscript preparation and review. DR, TH, and KC participated in the design of the study, provided methodological expertise, and revised the drafted manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

TH was on the steering committee that developed the TIDieR checklist and guide. There are no financial conflicts of interest to declare that may have influenced the results of this study.

Multimedia Appendix 1

Template for Intervention Description and Replication (TIDieR) checklist and examples of adequate reporting in included trial publications.

[PDF File (Adobe PDF File), 62KB - jmir_v19i12e410_app1.pdf]

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Abbreviations

CONSORT: consolidated standards of reporting trials
RCT: randomized controlled trial
SMS: short message service
TIDieR: Template for Intervention Description and Replication

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Appendix I: Chapter 6 focus group questions and vignettes

Table I-1: Focus group questions

1. Intro and ice-breaker - We want to hear your thoughts and experience with making diet changes in your life
2. What has helped you in the past to change your diet? - Has a dietitian been the one telling you to make these changes? *Or who do you go to for diet advice?* - What makes it hard to make these changes? - Do you ever feel like think you need more help when it does get hard, from your dietitian or someone else? - *What kind of help do you think you need?*
3. Have you been told to cut down your salt intake before? - How do you go following it? - What's the longest you have been able to follow it? - **What would help you to keep *eating less salt* in your diet?** o Can you tell me what has made it easier to make this change to your diet?
4. What other kidney diet changes do you find difficult to follow? - Do you feel you get enough information from your dietitian/other? Why, why not? - **Many kidney patients have told us previously that they prefer regular appointments or follow up to help them keep up with changes to their diet – what do you think about that?**
5. We are looking at ways to give you regular coaching and diet reminders – rather than booking into see the dietitian for review appointments at the hospital or clinic, some research has shown that the telephone and some technology (like a mobile) can mean you get this regular reminding and coaching – do you think this would be a good thing for you? - Which way would you prefer? o Face-to-face at the hospital/clinic; o Over the telephone; o Text/SMS; o Combination
6. If this was done face to face – waiting times could increase, and you might get less time with the dietitian – do you think the telephone or other types of technology would continue to help you make changes to your diet, *without the wait times*? - **Are you confident in using the telephone?** o Talk to family/friends? - **Are you confident in using a mobile phone?** o Apps? Text messaging? o Appointment reminders - **What about visiting a website?** o Have you ever used this as another source of information? o Can be used to put in your own diet information and then receive feedback o Online community with other kidney patients to support each other o What about email?
7. Would receiving regular telephone call appointments to get this coaching for diet advice interest you? - Would that help you to make those difficult diet changes? *(salt or other)*

- *Why can't you use this technology? (contingent)* - *What would make it easier?* - What would help you then to use more technology like this to follow low salt advice? *(contingent)* - **If you did receive telephone calls, would SMS reminders about the calls be helpful?** How often? - **What about SMS reminders reinforcing the call content be helpful?** - Do you think this could be a good way to get feedback on your diet?
8. If you were the dietitian and coaching someone else to make kidney diet changes, what advice would you give them? o What is important to know for them? - How often would you contact them? - Would you do it face-to-face or …. - *What if face-to-face meant you couldn't see them as often as you like?* - Is there anything else you would talk about?
9. This may seem very futuristic – but do you think this type of dietary service is a better way forward? - Is tracking blood tests something that might be useful to you? **10. Lastly, if this was offered as part of the care you receive – would you sign up for this? Why/not?**

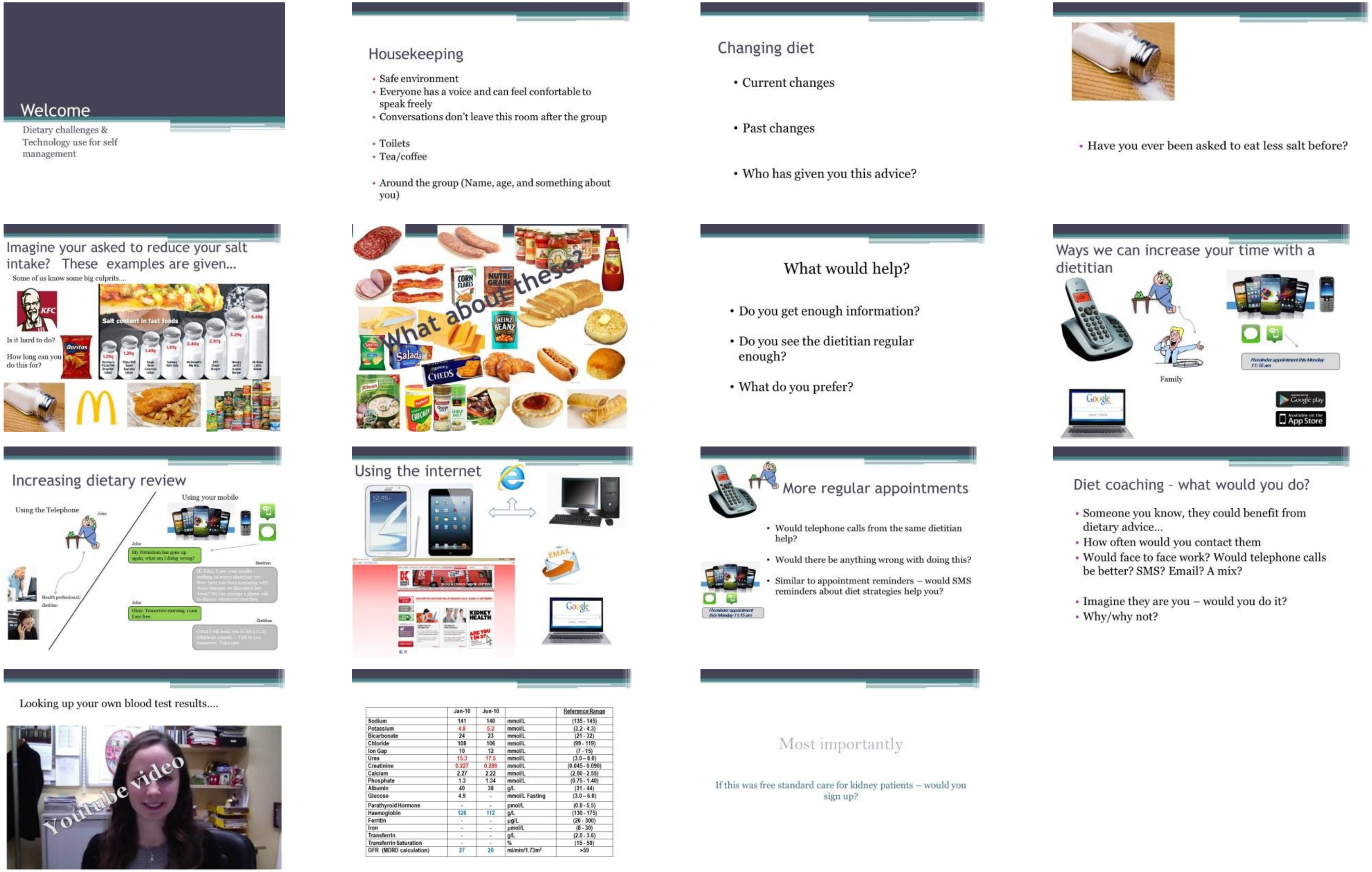

Figure I-1: PowerPoint show vignettes for focus group

Appendix J: ENTICE-CKD workbook given to the intervention and control groups

The ENTICE **Workbook** is based on the Australian Dietary Guidelines, Nutrition Education Materials Online (NEMO) and has been reviewed by renal dietitians, nephrologists and kidney health consumers prior to production. This **Workbook** was adapted from the iHELP and Living Well after Breast Cancer workbook, and is not to be reproduced without permission. Please contact Dr Katrina Campbell with any queries on (07) 3176 7938.

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Welcome to ENTICE

ENTICE is a healthy eating program for people with chronic kidney disease. It is designed to help you take care of your health and your kidneys, through healthy eating and regular physical activity. The ENTICE program is being offered as part of a research study to improve the ways we care for people with chronic kidney disease.

The focus of the program is to help you make gradual changes to your eating and physical activity habits that work for YOU – changes that become lifelong.

About the workbook

The ENTICE **Workbook** has information on achieving and maintaining healthy eating and physical habits to improve your kidney health.

Read through this **Workbook** at your own pace. You may receive phone calls or text messages from an ENTICE Coach who will provide extra support to help you work through the sections.

What do you want to get out of ENTICE?

In order to make positive lifestyle changes, it is important to think about what you would like to accomplish and how you will achieve it. Take some time to think about the following questions:

Why did you choose to participate in this program?

____

What do you hope to get out of this program?

____

What might get in the way of achieving your goals?

____

Section 1

Setting your goals and keeping track

"Strive for progress, not perfection" – Unknown

Your kidney health goals

The ENTICE program is about achieving and maintaining a healthy lifestyle. Your Doctor, Nurse or ENTICE Coach can help you to set realistic health goals.

My Target*		Week 0 Date:	Week 12 Date:	Week 24 Date:
LDL cholesterol	< 1.8 mmol/L			
HDL cholesterol	>1.0 mmol/L			
Total cholesterol	<4.0 mmol/L			
Blood pressure	<130/80 mmHg			
Fasting blood sugar				
Potassium	3.5-5.0 mmol/L			
Phosphate	0.81-1.45 mmol/L			
Weight				
Waist circumference				
Physical activity				

** Please not these health targets are just a general guide. Your Doctor, Nurse or ENTICE Coach will work with you to set personal target.*

How will I get there?

One of the most important steps to achieving your health goals is to set specific goals around changes you will make to your daily eating habits and physical activity.

You will be more likely to reach your goals, if you make them **SMART** goals:

Specific	What will you do?
Measurable	How much? How many?
Achievable	Are you able to do it?
Realistic	Will you be able to do it? Cost, time…
Timely	Is there a timeline? By when?

Rewards

Congratulating or rewarding yourself (but not a food-based reward) is a key part of staying on track with your goals.

Reward yourself when you make a change for the better; it's an excellent way to feel good about your success. It can also motivate you to keep eating healthy and being active.

Here are some reward ideas. Circle which reward(s) would work for you:

- Visit a friend
- Buy a new magazine or book
- Take an hour, just for you and do something you enjoy
- Go to a footbal game
- Take a fishing trip
- Go to the movies
- Take a weekend away camping
- Treat yourself to a massage or new hair cut
- Buy a new pair of walking shoes
- Buy yourself some new clothes

What other rewards could you use?

____

____

____

Setting a SMART goal

Use the following steps every time you set a **SMART** goal.

Step 1

Write down your **SMART** goal by filling in the blanks below:

For an Eating Well Goal

Starting on ______________ (day of the week)

I am going to ______________________________ at breakfast / lunch / dinner / snacks.

I am going to do this ______________ days this week.

Step 2

Write down what else you need to do to be able to meet this goal. For example, you need to go grocery shopping, plan evening meals for the week ahead on the weekend or buy a recipe book.

____

____

____

Step 3

Write down how you will reward yourself if you meet your goal this week.

____

____

____

Example of an eating well goal:

Starting next week, I am going to take lunch to work. I am going to do this 4 days per week (Monday to Thursday). I am going to write a shopping list, make sure we have lunch ingredients in the fridge before the week starts and get up 15 minutes earlier to make lunch for myself before I leave for work. If I can do this for a month I am going to get a subscription to my favourite magazine with the money I have saved.

Think of your eating well and active living **SMART** goals as important steps towards improving your kidney health.

Every time you set a **SMART** goal, think about your READINESS, IMPORTANCE, and CONFIDENCE:

How ready am I to make this change?

Not at all				Ready				Very ready	
1	2	3	4	5	6	7	8	9	10

How important is it to me?

Not at all				Important				Very important	
1	2	3	4	5	6	7	8	9	10

How confident am I that I will be able to achieve it?

Not at all				Confident				Very confident	
1	2	3	4	5	6	7	8	9	10

If your READINESS or IMPORTANCE ratings are less than 7, think about the pros and cons of making the change and discuss these with your Doctor, Nurse or ENTICE Coach.

If your CONFIDENCE is below 7, rethink your goal and how to change it so that your confidence increases. It is better to set yourself small goals that you are confident you can achieve and build on these, rather than big goals that are out of reach.

Keeping track

Like setting **SMART** goals, it is equally important to KEEP TRACK of your progress in order to keep your kidneys healthy.

Keeping track will help you:

- See if you are meeting your goals
- Stay motivated
- Identify when you start to slip back to old patterns

At the end of your **Workbook** there is some space for you to set and record your goals and space for you to write down your progress.

Section 2

Eating well for healthy kidneys

"Let food be thy medicine and medicine be thy food"

- Hippocrates

Diet and kidney disease

Eating a healthy diet is very important for people with all stages of kidney disease. Following a balanced diet can help slow the progression of your kidney disease.

Healthy eating plays a key role in:

- Controling your blood pressure
- Maintaining a heart healthy
- Achieving a healthy weight
- Managing cholesterol levels
- Managing blood glucose levels if you have diabetes

One of the jobs of the kidney is to clean waste products from the blood. Some of these waste products come from the foods that we eat. Depending on your stage of kidney disease, the level of potassium and phosphate in your blood may rise. Your ENTICE Coach, Nurse or Doctor may discuss some changes to your diet if you have problems with potassium or phosphate.

The following sections of your ENTICE **Workbook** will guide you though the components which make up a healthy diet. The ENTICE program will help you to gradually make changes to your diet to meet the daily recommended serves of fruit, vegetables and wholegrain breads/cereals.

To choose the right kinds of foods

Write down everything you eat and drink in the back of your ENTICE **Workbook**. This will help you identify the changes you can make to your diet. You can then use the **Workbook** tips and guidelines in the following sections to help you to identify smal and gradual changes to your diet to reach your healthy eating goals.

Choosing the right kind of foods

Healthy eating for good kidney health and wellbeing is about doing the following:

- **Enjoying a wide variety of nutritious foods from the five food groups**
- **Reduce your salt intake and limit intake of foods containing salt**
- **Limit your intake of foods containing saturated fat, added sugars and alcohol**
- **Drink plenty of water (unless advised by your doctor to follow a fluid restriction)**

Source https://www.eatforhealth.gov.au/guidelines/australian-guide-healthy-eating

The five food groups

- Vegetables
- Fruit
- Bread and cereals
- Dairy products
- Meat and meat alternatives

Eating a wide variety of these nutritious foods should be consumed every day to promote health and wellbeing and help protect against chronic disease.

While the total amount of food that is needed varies for every individual, the bulk of your diet should be made up of wholegrain breads and cereals, lean meat or meat alternatives, vegetables, and fruit.

People often eat bigger portions of foods than their body actually needs – this is often the case for foods like meats, pasta, rice and bread. Cutting back even a little on the foods you eat too much of can make a big difference. Often the foods we don't eat enough of are fruits and vegetables – which are great for filling you up!

What foods do you think you eat more than your body needs?

____

What foods do you think you don't eat enough of?

____

The table on the following page is a guide for the number of serves of foods from each the five food groups that you should aim to eat everyday.

Recommended daily serves	1 serve is equal to:	Why is this food group important?
Vegetables		
5	½ cup cooked vegetables 1 cup salad 1 small potato ½ cup legumes (lentils, beans)	Good source of carbohydrate, vitamins A and C, folate, minerals and fibre.
Fruits		
2	1 medium sized fruit (e.g. apple, banana) 2 pieces smaller fruit (apricot, kiwifruit)	Good source of vitamin C, folate, carbohydrate and fibre. * Try to choose whole fruits.
Grains and Cereals		
3 - 6	1 slice bread ¾ cup breakfast cereal ½ cup cooked pasta ½ cup cooked rice	Good sources of carbohydrate, fibre, B vitamins and iron. *Wholegrain or wholemeal varieties are the best choices.
Dairy (choose low fat varieties)		
2	1 cup milk 200g yoghurt 2 slices cheese (40g)	Good source of calcium, protein, riboflavin, vitamin B12.
Meat and Meat Alternatives		
2	65 g cooked lean red meat or chicken (size of a deck of cards) ½ cup cooked mince 100g cooked fish 2 medium eggs ½ cup legumes (lentils, beans)	Good source of protein, iron, zinc, niacin and vitamin B12. *Trim all meats or visible fat. *Choose fish twice a week

Indulgence Foods

Extra foods are those that aren't essential for providing our bodies with the nutrients, vitamins and minerals that it needs. These foods also tend to be high in energy so small changes to your intake of these foods can make a big difference to your daily energy intake.

Try to limit sweets, cakes, chips, takeaways, chocolate, soft drink and other high sugar/fat foods as much as possible. The more you limit these, the healthier your kidneys will be. As a general guide, you can have small amounts of these foods on 2-3 days per week.

Source:https://www.eatforhealth.gov.au/guidelines/australian-guide-healthy-eating

What extra or indulgence foods / drinks or do not support your healthy eating goals?

Can you identify changes you could make that would help you reduce your daily intake of these extra or indulgence foods?

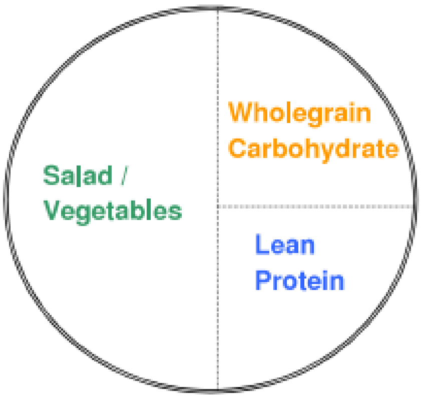
Is there one 'treat' that you couldn't live without? How often would you have this 'treat'? Could you reduce how often or how much you have of this 'treat'?

Getting the right portions for a balanced meal

When preparing a healthy meal it is important to consider the portion size of different foods. **The healthy eating plate picture** below is an easy way to help with portion control:

At main meals aim to fill

- *½ the plate with vegetables or salad*
- *¼ of the plate with a lean protein and*
- *¼ of the plate with a wholegrain carbohydrate*



Between meal snacks

Snacks

Snacks can be an important part of a healthy eating plan. The right kind of snack choice can help keep you going until your next main meal and avoid overeating at that meal.

However, It is important not to eat too many snacks, particularly foods high in sugar and fat.

If you get hungry, choose no more than two low calorie snacks each day.

Smart snack ideas

- 1 piece fruit
- 100g low fat yoghurt
- Vegetable sticks with 2 tablespoons of hummus / salsa / tzatziki dip
- 2 cups of air popped popcorn with no added fat or salt
- 1 scone with 1 teaspoon of jam or other spread
- 1-2 scoops low fat ice cream, e.g. Peter's Light & Creamy
- 2-3 wholegrain crackers (Vita Weat, Ryvita) with cheese

Example meal plan

Breakfast

- 2/3 cup cereal/porridge

OR

- 2 Weetbix/Vitabrits with ½ cup low fat milk

OR

- 1-2 slices of toast (suggested toppings = avocado, tomato, mushrooms, spinach or low fat cream cheese, poached/scrambled egg)

Lunch

- Sandwich (e.g 2 slices wholegrain bread with sliced roast beef or chicken & salad)

AND

- 1 serve fruit **or** yoghurt

Dinner

For a cooked meal;

- ¼ plate protein foods
- ¼ plate carbohydrate foods
- ½ plate vegetables/salad

Snacks

- 1 serve fruit
- 1 cup of air popped popcorn
- 1 tub of yoghurt

Sodium (salt)

Salt is made of sodium chloride and is written on food labels as sodium. It is the sodium that is bad for your health.

Blood levels of sodium are carefully controlled by the kidneys. Eating too much salt forces the kidneys to work harder and increases blood pressure. High blood pressure can increase can increase your risk of stroke, heart disease and kidney disease.

Remember all forms of salt e.g. rock salt, sea salt, salt flakes, pink salt, garlic salt, chicken salt, onion salt is still salt and can negatively affect your kidneys and health.

How much salt do I need each day?

Your body only requires a small amount of salt every day – less than a teaspoon. Most people consume double the amount of salt their body requires.

Most of the salt we consume comes from packaged foods, takeaway and restaurant meals.

Train your tastebuds

Allow your tastebuds time to adjust. Slowly cut down your salt intake over a few weeks to allow your taste buds to adjust. It may take up to 4-6 weeks for your taste buds to appreciate the natural flavours of food.

Tips to reduce your salt intake

- **Use salt sparingly - put the salt shaker away!**
- **Avoid adding extra salt to cooking or at the table**
- **Buy more fresh, unprocessed foods**
- **Season food with herbs and spices instead of salt**
- **Look for 'salt reduced' on labels**
- **Taste food before adding salt**
- **Shop by the labels – i.e. choose the lowest sodium variety you can**
- **Count your salt intake – Aim for < 1500 mg/day (~ 5 grams per day)**
- **Choose low salt foods – see below for examples of low salt foods to buy at the supermarket**
- **Limit takeaway and fast foods**
- **Limit to 2 slices of bread (or x 1 medium sized roll) per day**

Reduce your salt intake

Reducing your salt intake can be as easy as switching the types and brands of foods.

The following table ✓ represents **lower salt foods which are best choices** and ✗ represents **high salt foods that should be limited.**

Fruit	
✓ Fresh fruit	✗ Olives ✗ Tinned plums

Vegetables	
✓ Fresh vegetables ✓ Frozen vegetables ✓ Legumes ✓ Chickpeas ✓ Kidney beans ✓ Canned bean mix ✓ 'No added salt' canned vegetables	✗ Pickled vegetables ✗ Canned vegetables ✗ Tomato juice ✗ Marinated vegetables – eg sun-dried tomatoes ✗ Baked beans

Milk, yoghurt and cheese	
✓ Milk – all types ✓ Yoghurt, custard ✓ Ricotta cheese ✓ Reduced salt cheeses (ok in small amounts)	✗ Cheese spreads ✗ Cheese: cheddar, camembert, brie, parmesan feta,

Breads and cereals	
✓ Salt reduced bread ✓ Fresh and dried pasta ✓ 'No added salt' wraps ✓ Rolled oats, porridge ✓ Weetbix ✓ Sustain ✓ Just Right ✓ Puffed wheat ✓ Rice ✓ Rice and corn cakes ✓ Ryvita crackers ✓ Vita-Weat crackers	✗ Savoury crackers ✗ Sweet biscuits ✗ Croissants ✗ Pastry ✗ Cakes, scones, muffins ✗ Cornflakes ✗ Rice Bubbles ✗ Bran Flakes ✗ Tinned spaghetti ✗ Packet rice & pasta with flavouring

Meat, fish, chicken and eggs	
✓ Fresh, unprocessed lamb, beef, veal, pork, chicken, turkey, fish and seafood ✓ Eggs ✓ Tinned tuna / sardines / salmon in spring water	✗ Cured meats ✗ Smoked meats ✗ Salted meat ie. corn beef ✗ Bacon, Sausages ✗ Salami, frankfurts ✗ Meat pies, sausage rolls ✗ Ham, BBQ chicken ✗ Pizza ✗ Pate ✗ Chicken nuggets ✗ Anchovies ✗ Chinese foods ✗ Tinned fish in brine or tomato/sweet chilli sauce

Fats

✓ Unsalted butter	× Butter
✓ No added salt peanut butter	× Margarine
✓ Oil	× Peanut butter
✓ Avocado	
✓ No added salt or reduced salt margarines e.g. Becel, Sundew, Gold'n Canola, Flora	

Drinks, snacks & extras

✓ Milo, tea, coffee	× Sports drinks
✓ Unsalted nuts & seeds	× Soup, Bonox
✓ Jam, honey, syrup	× Dips
✓ Unsalted popcorn	× Cheese sauce
✓ Mint sauce	× Gravox
✓ Apple sauce	× Gravy
✓ "No added salt" sauces	× Vegemite, Marmite
	× Salted nuts and snacks
	× Crisps and pretzels
	× Mustard, pickles, relish
	× Most sauces - tomato sauce, tartare sauce, BBQ sauce, teriyaki, worcestershire sauce, soy sauce.

Source: https://www.health.qld.gov.au/nutrition/resources

Swap out the salt!

My high salt choice ____________________

My lower salt swap ____________________

My high salt choice ____________________

My lower salt swap ____________________

My high salt choice ____________________

My lower salt swap ____________________

My high salt choice ____________________

My lower salt swap ____________________

My health benefits of these swaps

____

Skills for making healthy choices

Making healthy choices for the long term means building skills in and around food. Having the skills to cook foods in a healthy way, what to look for when comparing products on supermarket shelves, and how to change your favourite recipes to make them healthier are all important for maintaining a varied healthy diet and achieving weight loss goals.

Label reading

Learning how to read food labels can help to make healthy choices, easy choices. The nutrition information on a food label can be useful in comparing similar products:

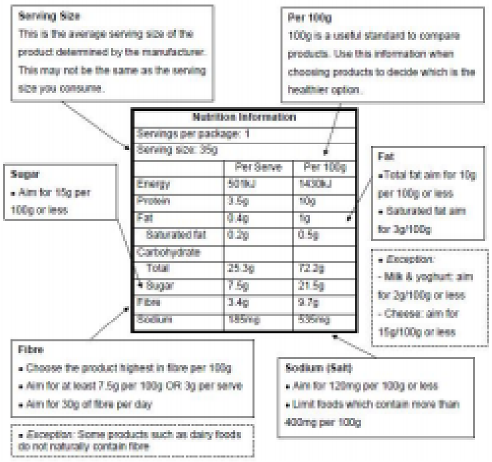
This can help you identify healthy choices that are:

- Lower in energy (kJ)
- Lower in saturated fat
- Lower in sugar
- Lower in sodium
- Higher in fibre

Compare the amount of nutrients in the "per 100g" column of the nutrition information panels of similar products to choose the healthier option.

Be aware that the serve size you have can sometimes be very different to what the serve size is on the packet.

See the examples on the following pages and compare the nutrition panels of these two similar products.



Source: https://www.health.qld.gov.au/nutrition/resources

Check the nutritional information table per 100g on food products to determine the sodium content of foods and compare products.

Low salt: 150mg per 100g or less - Best choice

Reduced salt: 400mg per 100g or less - Okay choice

What to look for on the label

- When buying canned fruit and vegetables, choose 'no added salt' and 'no added sugar' varieties
- If sugar content is high and the product contains dried fruit, check ingredients - only choose the product if fruit is listed before sugar in the ingredient list
- Choose healthy oils and spreads made from olive, canola, peanut, sunflower, soy or safflower
- When choosing canned fish and legumes look for "no added salt" varieties
- Choose "Indulgence foods" containing less than 600kJ per serve (that is the serve you would have of the product)

Nutrition claims – what do they really mean?

Food labels use different terms relating to nutrition and may be confusing. Here are some of the common ones:

- **"Light" or "Lite"** – May refer to the product as being light in flavour, colour or texture or lower in salt. These terms do not necessarily mean the product is low in fat or has fewer kilojoules.
- **"No cholesterol" or "Cholesterol free"** – This does not mean low-fat so check the fat content on the nutrition panel. Vegetable oils are naturally cholesterol free, but are 100% fat, so foods made with these can still be high in fat.
- **"No added sugar"** – No sugars have been added to the product but it may still contain natural sugars (such as those found in fruit). It does not mean it is lower in kilojoules.
- **"Low fat"** – Some products although low in fat compared to the original version may still be high in energy and may have more added sugar to make up for the decrease in fat.

Ingredients list

The ingredients list describes all the ingredients in the food item. Ingredients are listed in order of most to least by weight.

If sugar, fat or salt is listed within the first three ingredients, consider choosing a different product.

Spot the fat, salt and sugar

Some products will list fat, salt and sugar under different names on the ingredients list. Watch out for:

- Vegetable oil, vegetable fat, butter fat, milk solids, copha, tallow, lard, shortening, animal fat - **these are all names for fat**
- Raw sugar, brown sugar, sucrose, glucose, fructose, lactose, maltose, dextrose, malt, malt extract, corn syrup, high fructose corn syrup - **these are all names for sugar**
- Rock salt, sea salt, baking soda or powder, sodium bicarbonate, monosodium glutamate (MSG), sodium - **these are all names for salt**

Managing phosphate

What is Phosphate?

Phosphate is a mineral that combines with calcium to form the hard structure of bones and teeth.

Why is phosphate important?

Sometimes the kidneys may not remove extra phosphate from the blood which can cause itchiness from lumps of calcium that form in the bones and blood vessels. There are food choices you can make to help you lower your phosphate level.

Should I be restricting?

You should only be restricting phosphate if advised by your Doctor Nurse or ENTICE Coach. If you are taking binder medication, they should be taken just before each meal or snack containing foods high in phosphate. Please note that these medications are the best way to treat high phosphate.

A note on additives

Product ingredients

Reconstituted tomato (24%) (water, tomato paste), vegetables (23%) (chickpeas, potato, spinach, capsicum, onion), cooked brown rice (20%) (water, brown rice), canola oil, brown sugar, salt, thickener (1442), food acid (citric), spices (coriander, paprika, black pepper, cumin, cardamom, chili, ginger, cinnamon, nutmeg), **wheat** flour, garlic, onion powder, **whey** powder (from **milk**), natural colour (120, annatto extracts).
Contains wheat and soy

Top 5 most common Phosphorous-based food additives

Number	Additive name
450	Pyrophosphates
322	Lecithins
451	Tripolyphosphates
452	Polyphosphates
1442	Hydroxypropyl distarch phosphates

Any product with these numbers can raise your blood phosphate if your kidneys are not able to eliminate it from your blood.

Managing potassium

What is potassium?

Potassium is a mineral that helps your nerves and muscles work the right way.

Why is potassium important?

In some people with kidney disease, the kidneys may not remove extra potassium from the blood. Sometimes medicines and your diet can raise your potassium level. There are food choices you can make to help you lower your potassium level.

Should I be restricting?

You should only be restricting potassium if advised by your Doctor, Nurse or ENTICE Coach. Refer to section 78-79 of your **Workbook** for more information on potassium foods.

Monitoring symptoms – notify immediately:

- Fatigue or weakness
- Feeling of numbness or tingling
- Nausea or vomiting
- Short of breath
- Chest pain
- Heavy chest (skipping heart beats)

Please call or visit your local doctor if you experience any of the above symptoms.

Weight and kidney disease

If you are overweight, losing weight is important in managing kidney disease. You may also not be suitable for a kidney transplant and it can be harder to gain access for dialysis. Losing excess body weight will also help with diabetes control, blood pressure management, cholesterol levels and overall health.

Fad diets are not recommended for maintaining a healthy body weight. They are not practical to continue in the long run and can do serious harm to your kidneys and to your overall health.

If you are overweight and would like to lose weight your ENTICE Coach can help you achieve weight loss goals. Through the ENTICE program you will be guided by your ENTICE Coach, Doctor or Nurse to help make positive changes towards a healthier way of eating and a more active lifestyle which will help you achieve and maintain an optimal body weight for your health.

Alcohol

Alcohol provides extra calories and is nutrient poor and can lead to weight gain. Alcohol can be harmful to your health, the more alcohol you drink, the greater the risk of ill health.

Too much alcohol may also damage the liver and brain, and increase the risk of high blood pressure and heart disease and some types of cancers.

For this reason Australians are recommended to limit the amount of alcohol consumed to:

- 1 standard drink per day for women
- 2 standard drinks per day for men

With preferably **at least two** alcohol free days a week.

What is a standard drink?

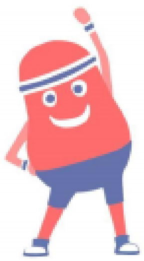
A standard drink contains 10g of alcohol, which is equal to:

- 100ml wine
- 285ml full strength beer
- 30ml spirits

Tips to help reduce your alcohol intake

- Quench your thirst with still or sparkling water, diet soft drink or plain, unflavoured mineral water instead of alcohol
- Sip your drink slowly. Put the glass down after each sip
- Take a break - alternate alcoholic beverages with non-alcoholic beverages
- Choose low alcohol alternatives i.e. light beer or reduced alcohol wine
- Choose a pot of beer or cider rather than a schooner or pint
- Order wine by the glass instead of by the bottle.
- Offer to be a designated driver
- Keep track of how much you are drinking – set limits and stick to them

Section 3
Active living



What is physical activity?

Any activity that gets your body moving makes your breathing more difficult and gets your heart pumping faster. You can be physically activity in many different ways.

Why should you be active?

Participating in regular physical activity and reducing sitting time is very important for your health and well-being.

Moving more and sitting less:

- Helps control / maintain your weight
- Gives you more energy
- Helps you sleep better
- Improves cholesterol and blood pressure
- Reduces your risk of developing heart disease, kidney disease, osteoporosis, diabetes and some cancers
- Makes doing daily tasks easier
- Increases strength and flexibility
- Reduces stress
- Helps you feel good

What benefits do you think you would get from being more active?

1.____

2.____

3.____

How much physical activity do I have to do?

Aim to do more!

Doing **ANY** physical is better than doing nothing. If you're currently not doing any or very little physical activity speak to Doctor, Nurse or ENTICE Coach about safe ways to get you moving more.

Remember you don't have to pound the pavement or sweat it out at the gym to see benefits!

- **Aim for 30-60 minutes on most days of the week - this can be accumulated in 10 minute blocks throughout the day**
- **Aim to sit less**
- **Break up long periods of sitting as often as possible**
- **Do muscle strengthening activities 2 days per week**

Sitting time

Aim to sit less!

While it can be nice to just sit and relax, too much sitting is not good for us – in fact, too much sitting has been linked with excess body weight and poor health.

On the positive side, because we do so much sitting, there are lots of opportunities to reduce it. Getting up and moving about as often as you can is a great way to get muscles working and your blood pumping.

How can I sit less and move more

Making some small changes to your every day routine can make a big difference to your health *(see the list of ideas in the table on the next page).*

How can I sit less and move more

Actions	I am doing this	I can make this change	I am not ready to do this
Stand up during TV ad breaks			
Walk on the spot or ride a stationary bike while watching TV			
Put the TV remote on top of the TV, so you have to get up and move to change the channel			
Get off the bus one stop earlier and walk the rest of the way			
Water the garden with buckets instead of a hose			
Take the stairs instead of the lift			
Plan an outdoor activity like walking, cycling or gardening			
Play with children or grandchildren outside			
Join a local walking group or sporting club			
Carry shopping bags inside one at a time			
Walk to the local shops or newsagent for your paper and milk			
Park your car further away from the shopping centre or your workplace			

When not to exercise

If you are new to physical activity have a health problem or are concerned about the safety of being more active, speak with your Doctor, Nurse or ENTICE Coach about the most suitable activities for you.

Do not participate in an exercise session if you have any of the following conditions:

- A temporary illness, such as a cold or viral infection, or if you are feeling unusually unwell
- Experiencing chest pain
- Unusual fatigue and/or muscle weakness
- Recurring leg pain or cramps
- Vomiting within the last 24-36 hours
- Feeling disorientated or confused
- Feeling dizzy, or having blurred vision or faintness
- Sudden onset of difficulty in breathing
- Foot or ankle sores that won't heal
- Any other unusual sensation

Please inform your Doctor, Nurse or ENTICE Coach if any of the above symptoms are present.

Section 4

Why is healthy eating important for my kidneys?

"To keep the body in good health is a duty… otherwise we shall not be able to keep our mind strong and clear" - Buddha

Diet is important for kidney disease risk factors

Did you know?

Less than 4% of the Australians meet the recommended daily intake for vegetables.

Research has shown that increasing your intake of vegetables by as little as **ONE** serve per day can help you live longer and stronger.

What about for people with kidney disease?

A small study with 147 people with the same condition as you (kidney disease) we asked to track their food intakes for five years via questionnaires.

The results found people with kidney disease who ate more servings of fruit and vegetables (compared to those people who didn't) were 27% less likely to need dialysis and on average lived longer.

Are you living with diabetes?

You are not alone! Almost 16.5 percent of people with kidney disease have diabetes.

Controlling your blood sugar levels is very important in protecting your kidneys. The ENTICE diet is based on the Australian Guide to Healthy Eating. It follows a diet based on low glycaemic index (low GI) carbohydrates, low saturated fat, low in added sugars and salt; which are all important dietary factors to control your blood sugar.

Do you have high blood pressure?

So too do 80% of people with CKD, and one third of the Australian population in general.

How can ENTICE help – sticking to your low salt diet. But more importantly the ENTICE diet is a whole diet approach, meaning all the nutrients within all the foods recommended to you work together to control blood pressure. If you can stick to the ENTICE diet approach (which is naturally lower in salt), you are well on your way to helping control your blood pressure and take the stress off your kidneys.

Do you have high cholesterol?

ENTICE is a diet low in saturated fat and high in fibre – which together can help reduce cholesterol levels.

Section 5

Plan for success

"Success is the sum of small efforts - repeated day in and day out." - Robert Collier

Getting support for living and eating well

Having people who support the changes you are making is really important. This could be a family member, friend, neighbour or colleague. It is a good idea to identify one or two support people.

Some examples of how the people around you can provide support are:

For diet:

- Eat healthy foods with you
- Not tempt you with indulgence foods
- Not offer you second helpings
- Congratulate your efforts to eat healthier foods
- Help you with shopping or cooking

For physical activity:

- Exercise with you (go for a walk together)
- Encourage you to do physical activity when you are tempted not to go
- Praise you when you have done your exercise

Who will your support person(s) be?

____

What support would be most helpful form the?

____

Remember to talk to them about this!

How, where and why you eat

There are a number of things that affect what we eat and our overall energy intake. It is important to be aware of, pay attention to and plan for:

- How you eat
- Where you eat
- Why you eat

Look back over your food reflections intake in checklist section of your ENTICE **Workbook** and ask yourself?

- Do I eat when I am hungry?
- Do I eat when I am with other people and in a social situation?
- Do I feel too full after some meals?
- Do I eat too quickly?
- Do I eat on the run or not sit down to eat meals and snacks>
- Do I eat in front of the TV or computer often?
- Do I often skip meals?

Managing slips

There are always things that get in the way of the best healthy eating and physical activity plans. This could be family commitments, social events, working extra hours, a trip away, or an illness. This can lead to a "slip" where you don't follow your plans.

There are three things to remember:

1. Slips are a normal part of lifestyle change
2. Slips are to be expected
3. Having a slip up on one occasion with your eating or activity will not ruin everything (no matter what it was)

A single slip isn't a problem. The important thing is to become aware of how you react to slips, so that they don't turn into permanent relapse (a return to your old habits).

A bad day doesn't have to lead to a bad week or month. Treat each day as a new opportunity to reach your goals.

When we have a slip it is easy to lose motivation and feel like it's not worth continuing. The key is to get yourself back on track as soon as you can.

So after you slip:

- Replace your negative self-talk with positive self-talk
- Remind yourself of the benefits healthy eating and physical activity
- Focus on all the positive changes you have made so far
- Talk to someone supportive
- Realise that even though you may have fallen off the track, you are not back at square one

Top tip - Learn from your slip!

Maybe you can avoid doing it again in the future or next time, manage it better.

How you can prevent slips?

Think and plan ahead.

You can help prevent a slip from occurring by?

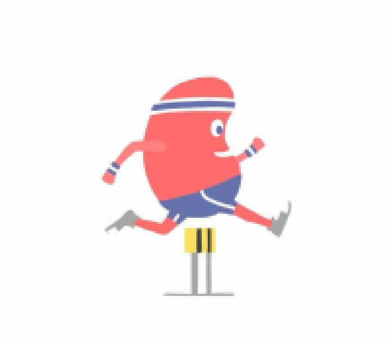
Identifying high risk situations that may lead to a slip, and;

Making a specific plan for how to manage these.

Section 6

Self-monitoring and setting goals

Use the following section of your Workbook to set some healthy eating goals and track your progress towards meeting the food intake goals for ENTICE.



My intake

Record the number of daily serves of each of the food groups you currently eat. You can then track your progress over the ENTICE program. See page 23 for information on serving sizes.

Daily serves	Baseline Date:	12 weeks Date:	24 weeks Date:
Vegetables			
Fruit			
Bread and cereals			
Diary products			
Meat and meat alternatives			
Extra foods			

Healthy eating actions

Actions	I am currently	I can make this change	I am not ready to change
The five food groups			
Vegetable intake			
Fruit intake			
Dairy intake			
Grain intake			
Meat /meat alternatives intake			
Indulgence food intake			

Actions	I am currently	I can make this change	I am not ready to change
Cooking and food preparation			
Cooking with fats and oils			
Label reading			
Drinks			
Alcohol			
Soft drink			
Water			

Actions	I am currently	I can make this change	I am not ready to change
Sodium			
Adding salt to the cooking			
Add salt at the table			
Takeaway foods			
Bread intake			
Processed food intake			
Other			
Takeaway foods			
Potassium			
Phosphate			

Activity – smart snacking

My snack choice

•

My snack swap

•

Nutrition benefits of this swap

•

My snack choice

•

My snack swap

•

Nutrition benefits of this swap

•

Reflections

Use the space below to reflect on successes, challenges and progress towards your goal

Week: **Date:**

Goal	Challenges	Solutions

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Reflections

Use the space below to reflect on successes, challenges and progress towards your goal

Week: **Date:**

Goal	Challenges	Solutions

70

Reflections

Use the space below to reflect on successes, challenges and progress towards your goal

Week: **Date:**

Goal	Challenges	Solutions

71

Reflections

Use the space below to reflect on successes, challenges and progress towards your goal

Week: **Date:**

Goal	Challenges	Solutions

72

Reflections

Use the space below to reflect on successes, challenges and progress towards your goal

Week: **Date:**

Goal	Challenges	Solutions

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Section 7

Additional healthy eating resources

"A clear vision, backed by definite plans, gives you a tremendous feeling of confidence and personal power"
– Brian Tracy

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Useful websites

- http://kidney.org.au/
- https://www.kidney.org/

Healthy eating

- https://www.eatforhealth.gov.au/
- http://www.nutritionaustralia.org/national/recipes

Healthy recipes

- http://www.qld.gov.au/health/staying-healthy/diet-nutrition/recipes/index.html
- http://daa.asn.au/for-the-public/smart-eating-for-you/recipes/browse/
- https://www.heartfoundation.org.au/recipes

Active living

- http://www.nprsr.qld.gov.au/get-active/index.html
- http://www.health.gov.au/internet/main/publishing.nsf/content/health-pubhlth-strateg-phys-act-guidelines

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Useful mobile phone or tablet APPS

Easy Diet Diary Renal

Available free of charge from iTunes for Apple products

FoodSwitch

Available free of charge from iTunes or Google play store for Apple or Android Products

My Fitness Pal

Available from iTunes or Google play store for Apple or Android Products

My Food Coach

Available from iTunes and Google play store for Apple and Android products

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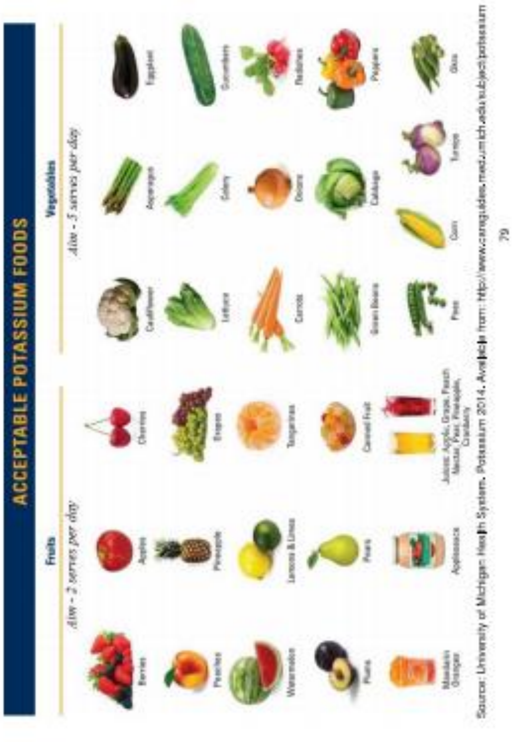

Low salt flavour combinations to try

Pork: garlic, lemon rind, coriander, apple sauce, ginger, mustard

Beef: bay leaf, thyme, mustard, sage, red wine

Lamb: mint, ginger, currant jelly, paprika, oregano, rosemary, garlic

Chicken: sage, tarragon, garlic, white wine, chili

Fish: lemon juice, lemon pepper, lime juice, chives, parsley, vinegar

Tomato: basil, garlic, black pepper, parsley, oregano

Potato: chives, paprika, mint, parsley, black pepper

Carrots: ginger, cinnamon, honey, parsley

Guide to healthier food choices when eating out

Below is a guide to making healthier food choices when eating out in different types of restaurants, including take-away.

In the following table ✓ represents **best choices** and × represents **less ideal choices.**

Asian (Chinese, Thai, Malaysian)	
✓ Stir-fry e.g. beef and black bean ✓ Steamed rice ✓ Sushi (limit soy sauce) ✓ Dishes in light sauces e.g. steamed fish, braised beef ✓ Vegetable-based dishes with chicken or seafood e.g. braised vegetables with chicken ✓ Rice paper rolls (limit soy sauce) ✓ Thai beef or chicken salad (limit nuts if you are watching your potassium)	× Fried noodles × Fried rice and coconut rice × Thai curries made with coconut milk × Deep fried or crispy duck or chicken × Satay chicken/beef/lamb × Spring rolls and dim sims × Tempura vegetables/meat/fish

Fish and seafood	
✓ Grilled or baked fish or grilled calamari served with salad	× Battered, crumbed or fried fish served with chips × Garlic and butter prawns × Fried calamari or seafood stick served with chips

Salads	
✓ Salad with oil free dressing ✓ Pasta salad with non-creamy dressing	× Salad with creamy dressing e.g. Caesar salad × Salad with bacon, croutons or cheese × Creamy pasta or potato salad × Coleslaw

Bakery	
✓ All bread ✓ Low-fat muffins ✓ Scones ✓ Crumpets ✓ Pita bread ✓ Chicken/ham/tuna rolls with no margarine or butter ✓ Fruit salad ✓ Gelati or sorbet in a small cup ✓ Apple or berry crumble ✓ Poached fruit with low fat custard	× Sausage rolls × Pies × Pizza × Cheese bread × Muffins × Donuts/slices/tarts × Croissants × Pasties (meat and vegetable)

Desserts	
✓ Fortune cookie	× Ice cream or sundae with fudge × Crème brulée × Cake and cheesecake × Chocolate mousse × Pudding

Source: https://www.health.qld.gov.au/nutrition/resources

Healthy recipes

Cinnamon and pear porridge (serves 1)

Ingredients

- ¼ cup rolled oats
- ¾ cup milk
- ¼ pear, chopped
- blueberries and ground cinnamon, to serve

Instructions

1. In a saucepan combine oats and milk. Bring to boil over low heat, stirring constantly.
2. Mix in pears. Stirring occasionally, until thick and creamy. Remove from heat.
3. Serve topped with blueberries and a dusting of cinnamon.

Nutrition information
Each serve of this recipe provides: • 1 serve grains / cereals • 1 serve dairy • 0.5 serve of fruit

Recipe adapted from taste.com.au

Cheesy omelette with mushroom (serves 2)

Ingredients

- 2 eggs
- 2 tablespoon water
- 150g grape or cherry tomatoes (cut in half)
- 1/4 cup continental parsley (finely chopped)
- 200g baby button mushrooms (cut in half)
- 1/4 cup extra water
- pepper (to taste)
- chopped continental parsley (extra for sprinkling)
- 50g reduced fat cheddar cheese (grated)

Method

1. Whisk eggs and water in a bowl until just combined.
2. In a separate bowl, combine cheese, tomatoes and 2 tablespoons of parsley.
3. Place half the cheese mixture over the omelette and fold in half. Slide onto a serving dish, keep warm, and repeat with remaining mixture to make another omelette.
4. Heat non-stick frypan and add mushrooms and water and sauté; until cooked through.
5. Season to taste with pepper and stir in remaining parsley.
6. Serve mushrooms on the cheesy omelette sprinkled with chopped parsley.

Option - serve with a toasted English muffin or slice of wholemeal bread. *Recipe adapted from http://www.nutritionaustralia.org*

Nutrition information
Each serve of this recipe provides: • 1 serve dairy • 0.5 serve meat / meat alternatives • 1 serve grains / cereals (if having with toast or muffin) • 1 serve of vegetables

Crackers with goat's cheese and cherry tomato

Ingredients

- x 2-3 Ryvita Multigrain biscuits **or** x 4 Vita-Weat 9 Grain biscuits
- 1 tbsp goats cheese
- 2 lettuce leaves, thinly sliced
- 4 slices of avocado
- 4 cherry tomatoes, sliced
- Pepper to taste

Method

1. Spread goats cheese evenly over each biscuit
2. Top with lettuce, sliced avocado and cherry tomatoes and pepper to taste

Nutrition information
Each serve of this recipe provides: • 1-2 serves vegetables • 1-2 serve grains and cereals

Other healthy topping ideas:

- Sliced tomato with pepper and fresh basil
- Thin spread of hummus with tomato
- Thin spread of reduced fat ricotta or cottage cheese or 80% fat free Philadelphia cream cheese with cucumber and tomato
- 1 slice reduced fat cheese with tomato and cucumber
- Sliced capsicum, tomato, spinach and mushroom with 1 slice reduced fat cheese
- 95 g can of salmon or tuna in spring water, flavoured or oil (drained) with lettuce, tomato and cucumber

Recipe adapted from taste.com.au

Vegetable and rice slice (makes 16 pieces)

Ingredients

- 1/2 cup medium-grain brown rice
- 1 large carrot, peeled, grated
- 1 large zucchini, grated 125g can corn kernels, drained, rinsed
- 1/4 cup roughly chopped fresh chives
- 1 cup grated reduced-fat tasty cheese
- 3/4 cup self-raising flour
- 4 eggs
- 1/2 cup reduced-fat milk

Method:

1. Preheat oven to 180°C/160°C fan-forced. Grease a 3cm-deep, 20cm x 30cm (base) lamington pan. Line with baking paper, allowing 2cm overhang at long ends.
2. Cook rice following packet directions. Drain. Cool for 20 minutes. Meanwhile prepare remaining ingredients.
3. Combine rice, carrot, zucchini, corn, chives, cheese and flour in a bowl. Whisk eggs and milk together in a jug. Add to rice mixture. Stir to combine. Spread into prepared pan. Bake for 35 minutes or until lightly browned and cooked through. Stand in pan for 20 minutes. Cut into 16 pieces. Serve.

Nutrition information
Each serve of this recipe provides: • 2 serves vegetables • 1 serve grains and cereals • 1 serve of meat / meat alternatives

Recipe adapted from taste.com.au

Lentil bolognaise (serves 4)

Ingredients

- olive oil cooking spray
- 1 brown onion, finely chopped
- 1 carrot, finely chopped
- 2 stalks celery, finely chopped
- 100g mushrooms, chopped
- 2 cloves garlic, crushed
- 2 teaspoons ground cumin
- 2 x 400g cans chopped tomatoes
- 400g can brown lentils, rinsed, drained
- 400g wholemeal spaghetti
- 2 tablespoons finely chopped parsley leaves

Method:

1. Heat a large non-stick frying pan over medium heat. Spray with oil. Add onion, carrot and celery. Cook for 5 minutes or until softened.
2. Add mushrooms, garlic and cumin and cook for another 2 minutes. Stir in tomatoes, bring to the boil, reduce heat to low and simmer for 10 minutes. Add lentils. Simmer for a further 5 minutes.
3. Cook spaghetti in a saucepan of boiling water. Drain and return to saucepan. Add lentil sauce and toss to combine. Serve in bowls, topped with parsley.

Nutrition information

Each serve of this recipe provides:

- 3 serves vegetables
- 1-2 serve grains and cereals
- 1 serve of meat / meat alternatives

Recipe adapted from http://www.healthyfoodguide.com.au

Chicken and veggie stir-fry (serves 4)

Ingredients

- 1 cup of canned pineapple, drained and juice reserved
- 2 tablespoons white vinegar
- 1 teaspoon honey
- ¼ teaspoon Chinese five spice powder
- 2 teaspoons of reduced salt soy sauce
- 2 teaspoons of fresh ginger (grated)
- 600g skinless chicken breast or thigh, sliced thinly
- 2 teaspoons of cornflour
- 2 teaspoons of olive oil
- 1 teaspoon sesame oil
- 1 medium carrot sliced
- 1 cup broccoli flowerets
- 1 cup snow peas (cut in half)
- 1 small red capsicum cut into thin slices)

Serve with ½ cup cooked rice for each person

Method

1. In a shallow dish combine pineapple juice, vinegar, honey, Chinese five spice, reduced salt soy sauce and ginger.
2. Add chicken and marinade for at least 1 hour or overnight. Drain chicken and reserve marinade
3. Add cornflour to the reserved marinade and mix until smooth and then set aside
4. In a large frying pan or wok, heat sesame oil and 1 teaspoon of olive oil. Add the chicken in small batches, stirring constantly, until no longer pink. Remove chicken from pan or wok and set aside.

5. Reheat pan with remaining teaspoon of olive oil and the vegetables and stir constantly for about 5 minutes (until vegetables are cooked but still crunchy)
6. Return chicken to the pan and add reserved marinade. Cook until sauce has thickened (few minutes), then add pineapple pieces and health through 1 minutes.
7. Serve with ½ cup of cooked rice for each person.

Nutrition information

Each serve of this recipe provides:

- 2-3 serves of vegetables
- 1 serve meat / meat alternatives
- 1 serve grains and cereals

Recipe adapted from the Renal Resource Centre NSW

Notes

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Notes

Notes

Notes

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Notes

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This **Workbook** is a part of The ENTICE study

Ethics number: HREC/16/QPAH/349

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Appendix K: Chapter 7 Utility and acceptability questionnaire

Table K-1. Utility and acceptability questionnaire completed at 6 months.

Thinking about the text message component of the ENTICE intervention; please answer the following questions (part A).
1. The text messages sent to me were useful in supporting me make a dietary change? ○ Strongly agree ○ Agree ○ Neither agree or disagree ○ Disagree ○ Strongly disagree
2. The text messages sent to me were easy to understand? ○ Strongly agree ○ Agree ○ Neither agree or disagree ○ Disagree ○ Strongly disagree
3. The text messages sent to me motivated me to change my diet ○ Strongly agree ○ Agree ○ Neither agree or disagree ○ Disagree ○ Strongly disagree
4. The text messages sent to me made me eat healthier? ○ Strongly agree ○ Agree ○ Neither agree or disagree ○ Disagree ○ Strongly disagree
5. The text messages sent to me made me exercise more? ○ Strongly agree ○ Agree ○ Neither agree or disagree ○ Disagree ○ Strongly disagree
6. How many of the text messages sent to you did you read? ○ All ○ Approximately three quarters ○ Approximately one half ○ Approximately one quarter ○ None
7. What did you do after receiving the text message? ○ Ignore it

- Read and saved
- Read and deleted

Thinking about the text message component of the ENTICE intervention; please answer the following questions (part B)

8. Did you share your text messages with family friends or your health care providers?
   - No
   - Yes; (please specify)
     - Spouse
     - Other family member
     - Doctor
     - Nurse
     - Other Health Care Professional

9. The text messages sent to me where worded in a suitable language
   - Yes
   - No

10. The text messages sent to me were too regular
    - Yes
    - No

11. The text message program (over 6 months) was long enough?
    - Yes
    - No

12. The text messages sent to me were at an appropriate time of the day/night?
    - Yes
    - No

Appendix L: Chapter 7 interview schedule for the semi-structured interviews

Table L-1. Semi-structured Interview Schedule.

Focus Point	*Key questions and prompts*
1. Warm Up, rapport building, experiences	I'm interested to hear about your story with a kidney condition. Would you be able to tell me about your story from when you first found out, how you felt and your journey up until now? - Can you tell me how you felt, or your initial reactions, when you were first diagnosed? - What was your experience with the healthcare system and dietitians before the ENTICE program? Can you talk me through how you got involved in the program? What happened? - How and why did you sign up? (Motivation? Knowledge? Priorities?) - Who influenced your decision to take part in the program? How? Why? - Did your doctor recommend the program? Did they have an influence on your decision to take part? (Support/pressure? Influence of medical professionals?) What happened after you signed up for the program? - Did you meet with a dietitian? How did you find that?
2. Barriers and facilitators of adherence to program	Before ENTICE, did you have any needs, challenges, concerns about diet? Could you briefly tell me about that? To what degree does the ENTICE program meet your needs or address what you want? How? Why? What do you like most/least about being involved in the program - why? What were some of the things that made the program easy/difficult to take part in? What are your thoughts on being in familiar surroundings while you're talking to [JK/MC]?
3. Telehealth delivery methods and frequency of contact	Let's move on to your experiences with the phone calls. - What did you expect from the calls and did they meet your expectations? - What are your thoughts on never having seen [coach name] and building a relationship with them? - How do you think using the telephone is different to seeing someone in person? Feel any different being in a familiar environment compared to a clinic? - Can you share some things that made the phone calls easier/harder than seeing [coach name] in person? - Were you able to make the calls at a suitable time - how? - What do you think about the frequency of the calls? – why? - How did you feel about the length of the calls? Did you feel you were rushed during the calls? - Do you have anything more to add about the phone calls? Let's talk about the text messages now, what did you think about getting the text messages from [coach name]? - Can you give me an example of a text message that you liked the

	most/least? - Do you think the text messages were necessary - why? - What do you think about how frequently you got the text messages? Why? - Do you have anything more to add about the text messages? You got a workbook at the start of the program. - What are your thoughts on the information in the workbook? – why? - Can you give me an example of something from the workbook that had an impact on you? (Why? Motivation? Knowledge?) - Did you have any difficulties understanding the information in the workbook? - Did you show the workbook to anyone? Who? Why? What did they think? - Do you have anything more to add about the workbook?
4. Usability of the program	Can you think of an example recommendation that [JK/MC] gave you about your diet or your lifestyle? - What are some things that helped you/made it hard for you to follow recommendations? – why?
5. Goal setting and self-monitoring	What are your thoughts on setting health goals? - How do you feel about goal setting? - Can you tell me about your experience with goal setting before the program? - Did you set goals in the program? When? Are you able to tell me about one of your goals? - Do you think ENTICE helped you to achieve your goals - why? One of the aims of ENTICE is to improve self-monitoring –do you know what self-monitoring means? (Stuff you'll do without people reminding you, like writing down or taking note of what you eat or how active you've been) - Do you find you do that? Why? - What impact do you think the program has had on your self-monitoring? (The way you go about it? How often?) - How confident do you feel with monitoring your diet? Why?
6. Behaviour change	You have made some changes to your lifestyle in order to meet your goals [example] - Will these changes be something that you'll continue to do? – how? why? - Can you tell me about your motivation to make changes before the program? - How and why did your motivation change during the program? - How do you feel about keeping motivated after the program? Do you feel like your daily activities have changed since before the program? How? (Eating behaviour? Purchasing of foods? How physically active you are?)
7. Experiences	- Did you feel that the recommendations from [coach name] were specific to you and nobody else? - Can you give an example of when you felt this way? - Were the recommendations clear? How? Why? - Do you understand why the advice was given to you? - Do you think the program and the telephone sessions were suited to your culture? - Did you share your experiences with the program with anybody else?

	Family, friends, other health professionals? How? Why? Did you find it helpful? Imagine you became director of the hospital and you had the power to improve the services for people with kidney disease. What would be the top 2 changes you would make to improve the care and support for people with kidney disease?
8. Closing	We would like you to help us evaluate the program to help improve it and the difference it makes to patients. Is there anything that you think would be important to mention that we haven't covered?